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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

Licensing Committee Report

Clarence Hiura, Chair
Ruth Conroy, Member
John Tilley, Member
Richard Benson, Member

Report of March 3, 2004

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy restructure the Competency Committee to a two-tier structure that would be a group of item writers to develop questions for the California Pharmacist Jurisprudence Examination (CPJE) and a core committee that would select and refine the items for the examination, select a cut-score and oversee the administration of the examination.

Discussion

The board's Competency Committee has created, overseen the administration of, and graded the California pharmacist licensure examination. Until January 2004, the examination was given twice a year and was comprised of 300 multiple-choice items and a 100-point, short-answer examination that had to be hand-graded.

This year, under the new examination structure created by SB 361, the board still must develop one examination, the 90-item multiple-choice CPJE. However, to prevent exam compromise, many more than 90 questions are being administered at any time. The Competency Committee develops these questions.

Appointment to the committee is an honor, but the work required of the committee is demanding. There is a minimum of seven two-day meetings annually, and additional outside time spent writing questions. Additionally, there are periodic subcommittee meetings to review performance statistics of the examination or perform other specialized tasks. Whereas the committee formerly hand-graded the short answer exam (this accounted for two of the seven two-day meetings), the committee is currently creating new items for the new examination structure.

Later this year, the committee will oversee a job analysis of the pharmacist profession; a survey of 2,000 pharmacists for each duty they perform and the importance of each task. From this job analysis, the committee develops the content outline for the examination. This job analysis must

be conducted every three to seven years, to assure that the exam remains valid for entry-level pharmacist practice.

The committee is carefully structured to ensure a balance of practitioners from all practice settings. In the last six months, there have been a number of changes as some members have rotated off the committee (they typically serve for eight years) and several others have resigned early due to other commitments. The current composition of 21 members is:

Schools of Pharmacy
- 1 active member UCSF
- 1 active member UOP
- 1 inactive member UOP
- 1 active member Western
- 2 active members USC

Board of Pharmacy
- Ken Schell
- Supervising Insp. Ming & Inspector Janice Dang

Community setting
- 5 active pharmacists
- 1 inactive pharmacist
- 2 vacancies

Inpatient setting
- 4 active pharmacists
- 1 inactive pharmacist

Managed care
- 1 active pharmacist

Typically the inactive members are those who are unable to attend meetings regularly. Additionally, the new pharmacy schools at Loma Linda and UCSD should be offered the chance to appoint members to the committee. In the past, each school has appointed two members.

Now that the needs of the new exam cycles are established, staff believes it is appropriate to convert to a new structure, a structure similar to the one used by NABP. The proposed structure would be a two-tier structure, a group of item writers to develop questions for the examination, and the core committee – the group that selects items and refines them for the examination, selects a cut score and oversees issues arising from administration of the examination.

The item writers would meet once annually for an item-writing workshop. Then, throughout the year, assignments to write questions in specific areas of the content outline would be assigned to them. The questions would be sent to the board in a secure manner. There would be no other meeting for this group of individuals.

The core committee would refine and revise the questions submitted by the item writers and review items selected for examinations to assure a balanced exam for any applicant. The committee would establish cut scores and review the performance of questions in the exam pool. When necessary, the members would also write items for the examination. This group would be smaller than the current committee (if the current Competency Committee was fully appointed, there would be 29 members). The proposed structure would be 19 members and membership would be as follows:

Schools of Pharmacy:	1 member each	6 members
Community Practice:		6 members
Institutional Practice:		5 members
Board Member:		1 member
Inspector:		1 member

Attendance at the meetings would be a requirement, and those who miss a certain number of committee meetings each year would be asked to become item writers because attendance at these meetings would not be necessary. There would continue to be seven meetings annually, but the board's item bank of usable items would grow greatly, facilitating examination administration. At some point in the future (perhaps two years), it could be possible to reduce the number of annual meetings of this group, perhaps to five or six meetings per year.

Terms would be for four years, with reappointment to another four years. The board's president would appoint all members. Appointment would require three letters of recommendation in addition to the applicant's curriculum vitae.

The costs for the new structure ($99,724) would be about the same as the costs for the current structure if 29 members were appointed to the committee and attendance remained at current levels – about 50 percent attending any full two-day meeting ($101,810). **(Attachment A)**

Restructuring the committee would reduce the burden placed on the members of the committee to attend 14 meeting days annually and write questions outside of the committee meetings. It would help prevent member "burn-out." Another benefit of using item writers for new questions would be a broader base of examination questions in the "bank." And as stated earlier, within two years, the committee could reduce its number of two-day meetings from seven to five each year if a large enough item bank exists.

RECOMMENDATION 2

That the Board of Pharmacy sponsor legislation to extend the provision that requires an applicant who has failed the board's pharmacist licensure examination four or more times to take an additional 16 units of pharmacy education. The provision would be extended to the board's next sunset review in 2006.

Discussion

Since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times, are required to take 16 units of education in pharmacy in a school approved by ACPE or by the board before they can retake the examinations. This provision will be repealed January 1, 2005, unless the sunset date for this provision is extended.

The board sponsored this provision to remove a number of applicants from the licensure examination who had repeatedly failed the examination – in fact; there were several applicants who had taken the examination more than 25 times. A major concern was that these individuals

were taking the examination only to memorize questions that could be provided to preparation course providers. The provision itself was modeled after a similar provision enacted for the dental examination.

When the provision was enacted in 1997, the board was also mandated to provide a report to the Legislature after June 1, 2004 and before December 31, 2004 on the effect of this provision in four areas. These areas are:

1. The number of applicants taking the examination and the number who fail the examination for the fourth time
2. The number of applicants who, after failing the examination for the fourth time, apply to take the additional 16 semester units of pharmacy education in California, and the number of these applicants who are accepted into the pharmacy education program.
3. The number of applicants who, after filing the examination for the fourth time, apply to participate in any pharmacy studies program, in or out of California, and the number of these applicants accepted by those programs.
4. To the extent possible, the school and country from which applicants graduated and the comparative pass/fail rates on the examination in relation to the school and country.

A copy of the draft report is attached. **(Attachment B)**

However, since the examination structure itself was greatly altered by last year's SB 361, staff requests that an extension in the sunset date for this provision be made. The reason for this is to allow the board time to evaluate the effect of the provision on the new examination structure. Attached is the proposed language. **(Attachment C)**

According to a recent legal opinion prepared by Departmental Counsel Dana Winterrowd, the four-time failure provision still affects those who take the CPJE and the NAPLEX. For those who have never taken the California licensure examination, they will have four opportunities to take and pass the CPJE and four opportunities to take and pass NAPLEX.

If someone had taken the old examination (before January 1, 2004) and failed it one or more times, these attempts do count when determining the four failures. For example, if someone failed the January and June 2003 examinations, he or she would have two more opportunities to pass the CPJE and two opportunities to take the NAPLEX. Once he or she reach four failed attempts, the individual would need to take the 16 units of pharmacy education before he or she could retake the examination.

RECOMMENDATION 3

That the Board of Pharmacy amend CCR, title 16, sec. 1719 to recognize those schools of pharmacy that have been granted "candidate" status by the Accreditation Council for Pharmacy Education (ACPE) for purposes of application for an intern registration and being admitted to the pharmacist licensure examination.

Discussion
At the January 2004 Board Meeting, the board agreed to accept "candidate status" accreditation by the ACPE as meeting sufficient standards for the board to issue an intern license to a student at Lake Erie School of Pharmacy.

This was the second time in one year that the board had to consider accreditation of a new pharmacy school because students were seeking California intern licenses. Both schools had limited accreditation status from the ACPE, which required specific board action to assure they could be issued intern licenses. At the board meeting, staff stated that they would suggest a more permanent resolution to the board. The proposal is to amend CCR, title 16, sec. 1719. **(Attachment D)**

Internship is an integral part of the pharmacy education of students. State licensing agencies look for ACPE accreditation as a means to assure the students are receiving particular (and approved) educational coursework before an intern pharmacist license is issued. This is especially critical for new schools, where there is only provisional ACPE accreditation (full accreditation will not be given until the first students have graduated from the school).

The ACPE Accreditation Manual, 9th Edition has the following definition of "candidate status:"

> **9.3.2 Candidate**. A new program that has students enrolled but has not had a graduating class may be granted Candidate status. The granting of Candidate status denotes a developmental program, which is expected to mature in accord with stated plans and within a defined time period. Reasonable assurances are expected to be provided that the program may become accredited as programmatic experiences are gained, generally, by the time the first class has graduated. Graduates of a class designated as having Candidate status have the same rights and privileges as graduates of an accredited program.

RECOMMENDATION 4

That the Board of Pharmacy consider the recommended changes from the Medical Board of California to the statewide protocol for pharmacists to dispense emergency contraception and adopt as an emergency regulation if necessary.

Discussion
On January 30, 2004 the Medical Board of California (MBC) considered the emergency contraception protocol approved by the Board of Pharmacy at its January 21, 2004 meeting. The discussion focused on the inclusion of a question regarding the last menstrual period in the protocol. Opposition to this question was articulated by the American College of Obstetricians and Gynecologists (the same opposition was indicated in their testimony before the Board of Pharmacy). The MBC delegated consideration of the protocol to a committee of its board, and Board of Pharmacy staff will participate in those discussions. It is expected that the MBC committee will meet prior to the Board of Pharmacy meeting in April so that the board may

consider any changes that are proposed. The MBC anticipates having the protocol on its agenda in May as an action item. **(Attachment E)**

It was also noted that the protocol once it is approved by both boards must be adopted as a regulation. The board may want to consider adopting the protocol as an emergency regulation so that it can be implemented more without further delay Otherwise it will take approximately another six months for implementation after the July board meeting. To adopt the protocol as an emergency regulation, the board must be able to demonstrate the immediate public health need.

RECOMMENDATION 5

That the Board of Pharmacy approve the request from Cedars-Sinai Medical Center for a waiver pursuant to CCR, title 16, sec. 1706.5 to conduct a study with UCSF, School of Pharmacy to determine the impact of using technicians checking technicians to fill unit dose cassettes on patient care.

Discussion
Dr. Ambrose, Professor of Clinical Pharmacy for UCSF, School of Pharmacy is requesting a waiver of CCR, title 16, sec. 1793.1(f) and 1793.7(b). The purpose of the waiver is to allow a pharmacy technician in a unit-dose drug distribution system to check another technician. Dr. Ambrose stated that this study is a logical sequel to the successful experimental program that evaluated technicians that concluded in December 2003.

This sequel study will evaluate the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional functions. Such functions require special expertise of pharmacists in the management of drug therapy, from which patients will benefit.

The Cedars-Sinai Medical Center (CSMC) is the sponsoring facility. The proposal requests that the board allow the "tech-check-tech" process to continue at CSMC, while UCSF measures the number and types of medication errors prevented during the equivalent time period that pharmacists would be check medication cassettes. Dr. Ambrose requests that the Board of Pharmacy grant the waiver for two years and that an interim report would be provided at one year. Representatives from CSMC also stated that they would continue to seek legislation to allow the "tech-check-tech" process. **(Attachment F)**

RECOMMENDATION 6

That the Board of Pharmacy sponsor a legislative proposal for inclusion in the 2004 omnibus bill that would give clear statutory authority to request information needed to evaluate the qualifications of any applicant.

Discussion
The board has applications for its 12 regulatory programs that require a range of different information from the various applicants. On the advice of counsel, requests for much of the needed information has not been included on the application forms because of a concern regarding the specific legal authority to request the information. Accordingly, staff developed a legislative proposal for inclusion in the 2004 Omnibus Bill. This proposal is intended to provide the board with clear statutory authority to request information needed to evaluate the qualifications of any applicant. This will allow the board to include necessary information on application forms without adopting regulations to do so. **(Attachment G)**

The proposal is to clarify the basic information that is requested on application forms, which is consistent with the relevant law requirements to obtain a license or permit from the board. Concern was expressed that the proposal may be too broad and the committee requested that language be provided to address those concerns.

NO ACTION

Implementation of North American Pharmacist Licensure Examination (NAPLEX and California Pharmacist Jurisprudence Examination (CPJE)

Both contracts to implement NAPLEX and the CPJE have been approved. The CPJE was approved March 11th and more recently, NAPLEX was approved April 2nd. Both exams will be available six days a week at designated testing locations across the United States. There will be 125 sites for the CPJE.

Application forms and instructions detailing the application process are available on the board's Web site. A Candidates' Guide handbook detailing procedures for taking the CPJE, what to expect at the test site, and how to study for the CPJE (including sample questions) has been developed. The board will place this handbook on its Web site, but Experior Assessments (the test administrator) will send a handbook to each candidate who has been qualified by the board to take the CPJE.

The NABP has a handbook containing similar information on its Web site regarding the NAPLEX that is available for downloading by applicants. There have been changes to the security requirements for admissions to the CPJE examination. Applicants are required to bring a government-issued identification (driver's license, state-issued identification card, military card) containing a recent photograph and a federal Social Security card. The name appearing on both of these identification cards must match exactly the name used to register for the CPJE, including designations such as "Jr." or "III," etc. If the applicant does not have the appropriate identification, then he/she will not be admitted to take the examination and will need to reschedule.

The board will release examination results within 15 days following the NAPLEX and approximately 30 days following the CPJE.

The board has made proposed regulation changes to its examination procedures to fully implement the NAPLEX and CPJE. The regulations have been noticed and the board will act on them at the April meeting. **(Attachment H)**

Overview of the Scholarship Process for Pharmacists

At the January meeting, the board agreed to pursue a statutory change to clarify the $25 contribution that can be made to the pharmacist loan repayment program. During this discussion, clarification was sought about the loan program and how it works. In response, the following information was prepared and provided to the Licensing Committee by Legislation Chief Paul Riches. Assembly Bill 2935 (Chapter 1138, Statutes of 2002) established the California Pharmacist Scholarship and Loan Repayment Program in the Office of Statewide Health Planning and Development (OSHPD). The bill established a mechanism for pharmacists and pharmacies to contribute $25 to a fund that would provide scholarships or loan forgiveness to pharmacists and pharmacy students who committed to serve in medically underserved communities.

The statute specifies that the program will only be implemented to the extent funding is made available. It permits both the contributions by renewing pharmacists and pharmacies and any other source of funding that can be identified and appropriated by the Legislature.

The bill also specifies that the program shall be administered using the criteria employed by the National Health Service Corps scholarship and loan repayment programs and excerpts from those program bulletins were provided. As a general matter, the programs provide funding to students and graduates who commit to provide health services in medically underserved communities for a two-year period. Funding is capped at $25,000 per year based on either the actual educational expenses or the total amount of qualified educational loans outstanding for the candidate.

Candidates are selected generally based on financial need and having characteristics that indicate a tendency to remain in the underserved community after their commitment has been completed. **(Attachment I)**

Report on the ACPE Evaluation of the Doctor of Pharmacy Program of Thomas J. Long School of Pharmacy

The Accreditation Council for Pharmacy Education (ACPE) is responsible for the evaluation of pharmacy education. The board accepts all ACPE accredited schools. When ACPE performs an evaluation of a California school, a representative from the Board of Pharmacy is invited to participate on the evaluation team.

Board Member Stan Goldenberg participated on the ACPE team that evaluated the Doctor of Pharmacy program of Thomas J. Long School of Pharmacy and Health Sciences at the

University of Pacific on February 17-19, 2004. He will report on the evaluation process and his experience at the April board meeting.

Report on the Workgroup on Compounding

Last April, the Board of Pharmacy agreed to form a workgroup with the Department of Health Services, State Food and Drug Branch to address pharmacy-compounding issues, including criteria used by the board to determine when compounding falls outside the scope of pharmacy practice. Because the Food and Drug Branch licenses manufacturers in California, they communicated the importance of their understanding of how the board notifies individuals when pharmacy-compounding activities falls outside the scope of pharmacy practice.

The Workgroup on Compounding held its first meeting on March 3, 2004. Dr. Schell chairs the committee with Board member John Tilley as a participant along with the board's supervising inspectors. A copy of the meeting summary is attached. **(Attachment J)**

Meeting Summary of March 3, 2004 (Attachment K)

Competency Committee Report (Attachment L)

Status Report on Committee Strategic Objectives for 2003/04 (Attachment M)

ATTACHMENT A

Summary of Costs

Members of the committee and item writers are considered "expert examiners" by the state, and are paid $19.21 per hour.

Costs for current structure:

Competency Committee: 29 members, 7 two-day meetings annually
(Assume 50 percent of members attend full meetings, 50 percent attend one day of each meeting)
$10,565 per meeting $73,955

Item writing (50 hours per year per member) $27,855

Total: $101,810

Costs for proposed structure:

Item writers: 20 members; 1 (one-day) meeting annually, plus 50 hours writing questions annually: $25,000

Core committee: 19 members, 7 two-day meetings annually ($10,675/meeting): $74,725

Total: $99,725

ATTACHMENT B

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STATE AND CONSUMERS AFFAIRS AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

-----D R A F T -------

Pursuant to California Business and Professions Code section 4200.1, the California State Board of Pharmacy is pleased to provide the following report detailing the impact of requiring candidates for pharmacist licensure who fail the licensure examination four times to take remedial education before they can retake the licensure examination. The board is required to submit this report after June 1, 2004, and before December 31, 2004.

Background:

Since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times have been required to take 16 units of education in pharmacy. This provision will be repealed January 1, 2005, unless the sunset date for this provision is extended.

This requirement was sponsored by the board to remove a number of applicants from the licensure examination who had repeatedly failed the examination – in fact, there were several applicants who had taken the examination more than 25 times. A major concern was that these individuals were taking the examination only to memorize questions that could be provided to preparation course providers.

This provision took effect July 1, 1998. To implement the statutory provisions, the board adopted a regulation that took effect November 4, 1998 (CCR, Title 16, section 1725). This regulation specifies that the remedial education of 16 units must be taken in a school of pharmacy approved by the American Council on Pharmaceutical Education (which in 2003 became known as the Accreditation Council for Pharmacy Education) or a school recognized by the board. The ACPE accredits schools of pharmacy in the United States. The board of pharmacy never separately recognized any school.

From July 1, 1998 until January 1, 2004, the board gave 10 examinations (January and June, 1999 - 2003). Each of these examinations was written and graded exclusively for California by the California Board of Pharmacy. The examination was developed by a team of 22 subject matter experts, under the guidance of a psychometric consulting firm selected to assure that the examination meets all required components for job relevancy and validity. Throughout this period, the licensure examination was comprised of two sections: a 300-point multiple-choice examination and a 100-point, short answer section. The multiple-choice examination was administered in two three-hour segments and the short answer segment was administered in a three-hour segment. Each examination was administered over a two-day period, in one location (Oakland or San Mateo), and given in a paper and pencil format.

In January 2004, there was a substantial change in the California pharmacist licensure examination made by SB 361 (Figueroa, Chapter 539, Statutes of 2003). The new provisions require the use of the National Association of Boards of Pharmacy Examination (called NAPLEX) and a second, California-specific and jurisprudence examination. Both examinations are given via computer, six days per week at testing centers nationwide. Testing began under the new format in late March 2004.

Because of the substantial difference in the licensure examinations after January 1, 2004, this report on examination performance uses any data from the prior form of the examination that was given between 1999 and 2003. Currently, the board proposes to extend the sunset date on section 4200.1 so that studies on its effect on candidates are chronicled under the new examination structure.

Data:

The board is required to report on four components. Each of these components is individually discussed below. For ease of presentation the required component appears in bold.

1. **The number of applicants taking the examination and the number who fail the examination for the fourth time.**

EXAM	TOTAL CANDIDATES	FOUR-TIME FAILERS	PERCENT
June 2003	1,284	12	0.9 percent
Jan. 2003	675	15	2.2 percent
June 2002	1,156	6	0.5 percent
Jan. 2002	536	21	3.9 percent
June 2001	1,165	12	1.0 percent
Jan. 2001	601	18	3.0 percent
June 2000	1,065	11	1.0 percent
Jan. 2000	537	14	2.6 percent
June 1999	950	9	0.9 percent
Jan. 1999	508	28	5.5 percent
	8,477 exam attempts	146 failed 4-times	1.7 percent

Approximately 2 percent of all exam attempts during the five-year study period were made by those who failed the licensure examination four times.

2. **The number of applicants who, after failing the examination for the fourth time, apply to take the additional 16 semester units of pharmacy education in California and the number of these applicants who are accepted in to the pharmacy education program.**

In California there were four schools of pharmacy during this period. Only one school, the University of Southern California, developed a program for students who failed the California examination four times. This was a special program offered in the Fall of 1998 through Spring of 2001. During this time, 63 individuals enrolled in the program and 49 completed the 16 units at USC.

Because admission to pharmacy schools is not within the board's jurisdiction or control, the board cannot report data on how many applicants applied to USC or other schools of pharmacy in California to complete 16 units of pharmacy education, and were denied entry.

3. **The number of applicants who, after failing the examination for the fourth time, apply to participate in any pharmacy studies program, in or out of California, and the number of these applicants accepted by those programs.**

As stated above, because admission to pharmacy schools is not within the board's jurisdiction or control, the board cannot report data on how many applicants applied to any schools of pharmacy to undertake supplemental pharmacy education. We are only aware of those candidates who completed the 16 units and reapplied to retake the examination in California.

The first group of "requalifers" (those who completed the 16 units of education and were again eligible to take the examination) were able to retake the California pharmacist examination beginning in January 2000. The number of candidates who passed the licensure examination following completion of this training is provided in parentheses.

Examination	California Schools Only Number Requalified	All Other Schools Number Requalified	Total
June 2003	2 (1)	13 (2)	15 (3)
January 2003	8 (1)	9 (3)	17 (4)
June 2002	10 (1)	5 (1)	15 (2)
January 2002	6 (0)	5 (1)	11 (1)
June 2001	19 (4)	7 (0)	26 (4)
January 2001	15 (0)	4 (1)	16 (1)
June 2000	24 (3)	4 (1)	27 (4)
January 2000	26 (2)	3 (1)	29 (3)

A total of 22 individuals of the156 individuals who requalified to take the examination, passed the licensure examination. This is 14 percent of those who requalified and retook the examination.

4. **To the extent possible, the school and country from which applicants graduate and the comparative pass/fail rates on the examination in relation to the school and country.**

   (Note: this is large table is still finalized at time the board packet was prepared. It will be distributed as a separate table at the board meeting.

ATTACHMENT C

Board of Pharmacy
Draft Amendments to Section 42001.1

Amend Section 4200.1 of the Business and Professions Code, to read:

4200.1. (a) Notwithstanding Section 135, commencing January 1, 2004 ~~July 1, 1998~~, an applicant who fails to pass both the North American Pharmacist Licensure Examination after four attempts and the Multi-State Pharmacy Jurisprudence Examination for California after four attempts ~~the examination required by Section 4200 after four attempts~~ shall not be eligible for further reexamination until the applicant ~~has~~ successfully completes at least ~~completed a minimum of~~ an additional 16 semester units of education in pharmacy. The applicant shall complete a minimum of 16 semester units or the equivalent from pharmacy coursework as approved by the board. When the applicant applies for reexamination, ~~he or she~~ the applicant shall furnish proof satisfactory to the board that he or she has successfully completed all of the requirements of Section 4200. For the purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004 as a failing score on both the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination.

(b) From January 1, 2004 ~~July 1, 1998~~, to July 1, 2006 ~~2004~~, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions and Consumer Protection ~~Legislature after June 1, 2004, and~~ before September 1, 2006 ~~December 31, 2004~~, regarding the impact on those applicants of the four-attempt limit imposed by this section. The report shall include, but not be limited to, the following:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, apply to take the additional 16 semester units of pharmacy education in California, and the number of these applicants who are accepted into the pharmacy education programs.

(3) The number of applicants who, after failing the examination for the fourth time, apply to participate in any pharmacy studies program, in or out of California, and the number of these applicants accepted by those programs.

(4) To the extent possible, the school and country from which applicants graduated and the comparative pass/fail rates on the examination in relation to the school and country.

(c) This section shall remain in effect only until January 1, 2008 ~~2005~~, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008 ~~2005~~, deletes or extends that date.

ATTACHMENT D

Board of Pharmacy
Draft Amendments to Title 16, Section 1719
Approved Schools of Pharmacy

§1719. Requirements for Admission to Examination & Approved Schools of Pharmacy.

(a) Applicants for the pharmacist licensure examination shall have graduated from an approved school of pharmacy. ~~completed all requirements for graduation from a school of pharmacy accredited American Council on Pharmaceutical Education or recognized by the Board.~~
(b) An approved school of pharmacy is one either accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or a pharmacy school separately recognized by the board.

~~(b) All candidates for the pharmacist licensure examination shall have completed a minimum of 1,000 hours of experience prior to applying for the examination.~~[1]
~~(c) All candidates for the pharmacist licensure examination who are graduates of a foreign pharmacy school (any school located outside the United States of America) must demonstrate proficiency in English by achieving a score specified by the board on the Test of Spoken English administered by the Educational Testing Service. For candidates taking the Test of Spoken English after June 30, 1995, a score of at least 50 must be achieved. For candidates taking the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.~~[2]

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 851, 4005 and 4200 of the Business and Professions Code.

The ACPE Accreditation Manual, 9th Edition has the following definition of "candidate status:"

9.3.2 Candidate. A new program that has students enrolled but has not had a graduating class may be granted Candidate status. The granting of Candidate status denotes a developmental program, which is expected to mature in accord with stated plans and within a defined time period. Reasonable assurances are expected to be provided that the program may become accredited as programmatic experiences are gained, generally, by the time the first class has graduated. Graduates of a class designated as having Candidate status have the same rights and privileges as graduates of an accredited program.

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[1] This language is stricken to conform with changes introduced in the 2004 Omnibus Bill.
[2] This language is stricken to conform with changes introduced in the 2004 Omnibus Bill.

ATTACHMENT E

State of California Department of Consumer Affairs

Memorandum

To: Board Members Date: April 13, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Emergency Regulations

Background

In its January 2004 meeting, the board approved a draft statewide protocol that would allow pharmacists to furnish emergency contraception without a prescription. This protocol was established by the passage of Senate Bill 490 (Chapter 651, Statutes of 2003) which requires that the protocol be approved by both the Board of Pharmacy and the Medical Board of California. The Medical Board considered the draft approved by the Board of Pharmacy in January and has requested changes to the document (see Attachment 1 for the Medical Board draft, and Attachment 2 for a marked up version of the Board of Pharmacy-approved draft reflecting the proposed Medical Board changes).

In the course of developing and reviewing the protocol, counsel has indicated that the protocol would have to be adopted in regulation before it could become effective. The normal rulemaking process requires approximately 12 months to complete which would delay implementation of the statewide protocol substantially if the board accepts the modified protocol. As such, staff recommends adoption of the regulation as an emergency regulation.

Emergency Regulations

California law does permit the adoption of emergency regulations if:

> "a state agency makes a finding that the adoption of a regulation or order of repeal is necessary for the immediate preservation of the public peace, health and safety or general welfare" (Government Code Section 11346.1(b))

Emergency regulations would remain in effect for 120 days while the board would have to complete the normal rulemaking process (notice, hearing, adoption, submission). If this process is not completed within the allotted time frame (extension for a limited period of time may be requested), the emergency regulation is repealed. To comply with this timeframe, the board would have to notice the permanent regulation and adopt it at its July 2004 board meeting.

Grounds for Emergency

Under current law only pharmacists who have established a protocol with an individual prescriber may furnish emergency contraception without a prescription. At this time approximately 800 pharmacies in California have at least one pharmacist with such a protocol in place. Pharmacists and activists involved in this process report that finding a physician to sign a protocol agreement is a significant barrier to broadening access to emergency contraception in this manner.

The establishment of a statewide protocol would open up access to emergency contraception in every one of the over 5600 community pharmacies in California. A pharmacist could use the statewide protocol after completing one hour of approved continuing education in furnishing emergency contraception.

Emergency contraception can prevent unwanted pregnancies with a high degree of effectiveness and has no dangerous side effects. In fact, an FDA advisory committee recently recommended the approval of one emergency contraceptive product for over-the-counter status. If unwanted pregnancies are not prevented in this manner, a woman who became pregnant and did not want to carry the child to term would have to obtain an abortion which poses significantly greater risks to the health of the mother at much greater cost to the healthcare system. Broader access to emergency contraception through community pharmacies would clearly preserve the public health and welfare.

Action Item

To proceed with an emergency regulation, the board must:

1) Declare that the lack of a statewide protocol constitutes and emergency.

2) Approve the proposed protocol regulation.

Attachment 1

Protocol for Pharmacists Furnishing Emergency Contraception (EC)
MBOC Version

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

Procedure: When a patient requests emergency contraception the pharmacist will ask and state the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medical record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products appended to this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

Attachment 2

Draft Protocol for Furnishing Emergency Contraception
Edits Proposed by the Medical Board

Protocol for Pharmacists Furnishing Emergency Contraception (EC)

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

Procedure: When a patient requests emergency contraception the pharmacist will ~~assess the need for emergency contraception by determining:~~ ask and state the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

~~o If patient is requesting EC for emergency use or advance need.~~
~~o Date of last menstrual period to help rule out pregnancy.~~
~~o If patient is allergic to any medications.~~

~~For emergency use:~~

~~o If patient had unprotected intercourse within the time limits established for effective use of emergency contraception.~~

~~When the pharmacist determines that furnishing emergency contraception is appropriate, the~~ The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medical record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

~~Timing: EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. The pharmacists should counsel clients that :~~

- ~~EC effectiveness declines gradually over 5 days~~
- ~~EC use will not interfere with an established pregnancy~~

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

Advanced Provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products appended to this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

Appendix 1 -- Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Brands and Doses Of Oral Contraceptive Tablets Used For Emergency Contraception

Dedicated Emergency Contraception				
Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynétics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart *)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)*
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60

Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

Appendix 2 -- Sample list of Anti-Emetics for Use with Emergency Contraception.

Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Appendix 3 – Title 16, Section 1707.1 of the California Code of Regulations

§1707.1. Duty to Maintain Medication Profiles (Patient Medication Records).

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;
2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;
3. The date on which a drug was dispensed or refilled;
4. The prescription number for each prescription; and
5. The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

Authority cited: Sections 4005, 4121 and 4122, of the Business and Professions Code.
Reference: Sections 4005, 4121 and 4122, of the Business and Professions Code.

ATTACHMENT F

CEDARS-SINAI MEDICAL CENTER®

March 30, 2004

Patricia F. Harris
Executive Director
California State Board of Pharmacy
400 "R" Street, Suite 4070
Sacramento, Ca 95814-6200

Dear Ms. Harris,

We would like to request the opportunity to discuss a waiver, pursuant to California Code of Regulations, sections 1706.5 (Experimental Program) and 1793.7 (b) (Requirements for Pharmacies Employing Pharmacy Technicians), at the April 21, 2004 meeting of the California State Board of Pharmacy. The purpose of the waiver is to enable Cedars-Sinai Medical Center to conduct a study in collaboration with the University of California, San Francisco School of Pharmacy to determine the impact of technicians checking technician filled unit dose medication cassettes on patient care. Please free to contact me should you have any questions. Thank you for your consideration.

Sincerely,

Rita Shane, Pharm.D., FASHP
Director, Pharmacy Services
Cedars-Sinai Medical Center
Assistant Dean, Clinical Pharmacy
UCSF School of Pharmacy
Los Angeles, CA
310-423-5611
shane@cshs.org

cc: Peter Ambrose, Pharm.D.
Frank Saya, Pharm.D.

March 6,2004

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, Ca. 95814

Dear Board and Licensing Committee Members,

It has come to my and other California residents attention that at the March 3,2004 Board meeting Cedars-Sinai Medical Center (CSMC) requested,in conjunction with the UCSF School of Pharmacy, a waiver to conduct a study of the impact of Pharmacy Technicians checking Pharmacy Technicians. The Board knows full well that since approximately May 1998 there has been a pilot study involving this same subject with various institutions (until recently terminated)! Just what "additional information or facts" does the Board and CSMC hope to determine after a pilot study lasting over 4 years! To repeat similar studies via a waiver is simply a guise by Cedars Sinai to save money at the expense of patient safety (and possibly taxpayers expense)! Surely it need not be pointed out to the Board and Licensing Committee the problems at California hospitals regarding medication errors (see enclosed L.A.TIMES article of March 5,2004). Please remember that Cedars-Sinai is a private institution and by granting a waiver to them the Board may be discriminating against other institutions who also are subject to similar expenses.

Futhermore, since UCSF School of Pharmacy is a State institution,it is possible that the funding for this study may involve taxpayer funds at a time of California's worst budgetary crises! Thus to grant a waiver at this time to Cedars-Sinai would be unconscionable! It is with these facts in mind,that if a waiver is granted, there will be no alternative but to request the State Attorney General to investigate these actions from a health and safety issue as well as the possibility of the frivolous wasting of State funds at a time of severe budgetary constraints.

Sincerely,

"A CONCERNED TAXPAYER"

CC. Bill Lockyer, California State Attorney General
CC. Arnold Schwarzenegger,Governor

King/Drew Is Again Assailed Over Prescription Drug Flaws

State inspectors are second group in a week to chastise the hospital for giving the wrong medication to a patient with meningitis.

By CHARLES ORNSTEIN
Times Staff Writer

Government health inspectors plan to cite Martin Luther King Jr./Drew Medical Center for serious flaws in the way prescription drugs are managed at the public hospital in South Los Angeles.

The findings follow an investigation into an error last month in which the wrong patient received a potent anti-cancer drug for four days.

The California Department of Health Services this week told King/Drew hospital it would be cited for failing to administer medication accurately, delaying care and services for a patient, failing to clarify medication errors, and lacking "general oversight" over pharmaceutical services, according to a summary of the findings provided to Los Angeles County supervisors by the county health department.

The state hospital inspectors were the second group of regulators in a week to chastise the hospital for giving the anti-cancer medication Gleevec to a patient with meningitis.

Representatives from the California Board of Pharmacy cited the hospital for the error several days ago.

The state health department outlined its findings at a meeting with King/Drew leaders Wednesday night and will follow up with specific details in writing.

The expected citations would put the hospital at increased risk of losing federal funding for Medicare and Medi-Cal patients, but King/Drew would be given the chance to respond before any action was taken.

King/Drew, a 233-bed hospital in Willowbrook, just south of Watts, already faces the loss of federal funding because of unfavorable inspections in other areas.

In recent months, state and federal inspectors have cited the hospital for a pattern of lapses in care, including the deaths of five patients last year after a host of errors by nurses and other employees.

Medication errors are fairly common in hospitals, but county health officials said the latest mix-up at King/Drew Medical Center was more serious because it was not caught for several days.

"If you look at medication errors, generally you'll see wrong dosages or missed medications, but usually it's caught quicker and resolved," said Fred Leaf, the county health department's chief operating officer, who is leading a crisis management team at the hospital.

"This went on for four days," Leaf said.

"That to me signifies a little greater problem in terms of staff competence in the area of medication management."

Leaf said his agency was still weighing discipline for the employees involved.

"Obviously, these nurses didn't know what the drug was and they didn't make an effort to know what the drug was, so they didn't follow their own nursing practice appropriately," Leaf said.

From now on, two King/Drew nurses must check to ensure the accuracy of orders for high-risk drugs and a nursing supervisor must review drug orders each shift.

Doctors are also being instructed to play a greater role in ensuring patients receive the right medications.

UCSF
University of California
San Francisco

February 17, 2004

LA/OC Area Clerkship Program
Department of
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Long Beach Memorial
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Patricia F. Harris
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California State Board of Pharmacy
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Re: Study Proposal (attached)

Dear Ms. Harris:

As a result of the successful experimental program that evaluated pharmacy technicians in a unit-dose drug distribution system ("tech check tech") that concluded in December at Long Beach Memorial Medical Center and Cedars-Sinai Medical Center, we would like to propose a logical sequel study. The sequel study will evaluate the impact of pharmacists in the prevention of medication errors associated with prescribing and administration of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional functions. Such functions require the special expertise of pharmacists in the management of drug therapy, from which patients will benefit.

The members of the Board were very complimentary during my final presentation of the results from the previous experimental study, and the attached proposal is in response to the general feeling of the Board that they now have the data and confidence to move the profession forward in the best interest of patient care. Further, I believe the proposed study will be of benefit to prescribers and nurses in caring for their patients.

The proposed study would be conducted at Cedars-Sinai Medical Center (CSMC) under my direction as the sponsoring faculty member from the UCSF School of Pharmacy. The proposal requests that the Board allow the "tech-check-tech" process to continue at CSMC, while we measure the number and types of medication errors prevented during the equivalent time period that pharmacists would be checking medication cassettes.

I will be available to present this new proposal to the Board, and the co-investigators from CSMC will also be available. Thank you for your time and consideration.

Respectfully submitted,

Peter J. Ambrose, Pharm.D.
Professor of Clinical Pharmacy

Proposal for an Experimental Project

Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medications in the Hospital Setting

A Collaborative Study Between

UNIVERSITY OF CALIFORNIA,
SAN FRANCISCO
SCHOOL OF PHARMACY

and the

Pharmacy Services Department of

CEDARS-SINAI MEDICAL CENTER

February 17, 2004

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Introduction

During the previous experimental program which demonstrated the safety of technicians checking technician-filled medication cassettes, (Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes. Peter J. Ambrose, Frank G. Saya, Larry T. Lovett, Sandy Tan, Dale W. Adams, Rita Shane, Am J Health-Syst Pharm. 2002; 59:1183-8.)[i] Cedars-Sinai Medical Center pharmacists documented an increase in potential medication errors prevented by pharmacists' clinical interventions as a result of their time that was redeployed to the patient care areas. The purpose of the proposed new experimental program is to determine the number and types of medication errors prevented at the prescribing step (order written by the physician) and at the administration step (medication administered by the nurse) of the medication use process during the equivalent time period that the pharmacists would formerly be checking medication carts. For the purpose of this study, the terms potential "medication error" and "adverse drug event" will be used interchangeably. In order to perform the experimental program, a waiver to enable resumption of certified technicians checking technician filled-medication carts is requested. The same certification and quality assurance processes described in the previous experimental program would be used during this study.

Background

In 1999, the Institute of Medicine published the report, "To Err is Human: Building a Safer Health System," which documented that 44,000-98,000 patients die each year as a result of medical errors in hospitals.[ii] The report indicated that medication-related errors occur frequently in hospitals and cited a study which demonstrated that approximately 2 out of every 100 admissions resulted in a preventable adverse drug event. An analysis of the incidence of potential and actual adverse drug events demonstrated that errors resulting in preventable events occurred primarily at the prescribing step (56%) and at the medication administration step (34%) of the medication use process, followed by the transcription (6%) and dispensing processes (4%).[iii]

Recent studies have demonstrated the value of pharmacists in reducing adverse drug events in the ICU, pediatrics and medicine units. In these studies, pharmacists' participation on patient rounds was associated with a significant reduction in adverse drug events.[iv,v,vi] In 1997, Lesar, et al, reported the results of a nine-year experience with pharmacists detecting medication prescribing errors. Over this time period, the annual number of errors detected increased from 522 in 1987 to 2,115 in 1995 – a three hundred percent increase.[vii] The rate of errors-per-order-written also increased significantly during this time period. The Lesar study indicated that improving the availability of pharmacists in the hospital setting was important in reducing errors, especially since the literature has documented "an

association between the level of pharmacy services and reduced length of stay and mortality." The study concluded that there is a "progressively increasing risk of adverse drug events in hospitalized patients" and that new errors were intercepted as new medications became commercially available. Of note, new drug approval times have decreased from a median of 22 months in 1992 to a median of less than 12 months in 1999.[viii] Additionally, over the last 5 years, an average of 79 new drugs were approved each year. The number of FDA warnings has increased from an average of 24 warnings per year prior to 1999 to 41 per year over the past 5 years.

In 2001, the Agency for Healthcare Research and Quality released a report "Making Health Care Safer: A Critical Analysis of Patient Safety Practices" which evaluated practices associated with improved patient safety based on evidence in the scientific literature.[ix] Chapter 7 of this report, entitled "The Clinical Pharmacist's Role in Preventing Adverse Drug Events", acknowledges the "well-documented benefits of pharmacists and promising results in the inpatient setting" and recommends further focused research in this area. More recently in 2003, the National Quality Forum released a consensus report on 30 healthcare safe practices. One of these practices is having pharmacists in acute care (hospital settings) actively participate in the medication use process and "at a minimum, be available for consultation with prescribers on medication orders".[x] This recommendation was adopted this year by the Leapfrog Group, a consortium of over 150 organizations that represent 34 million consumers as part of their recommendations for improving patient safety in hospitals.[xi]

The nursing shortage has been well documented in the last several years.[xii,xiii] In September 2000, errors associated with inadequate staffing and insufficient training became a public issue with the Chicago Tribune headline: "Nursing Mistakes Kill, Injure Thousands."[xiv] This was the first in a series of 3 articles that the Tribune published on nursing errors resulting from excessive patient care responsibilities, use of temporary staff and lack of training. The majority of errors described in these articles involved medications. In November 2003, the Institute of Medicine released "Keeping Patients Safe: Transforming the Work Environment of Nurses" as a follow up to the aforementioned report "To Err is Human." This study was conducted upon the request of the Department of Health and Human Services and the Agency for Healthcare Research and Quality to determine key aspects of the nurse's work environment that have an impact on patient safety and potential improvements.[xv] The report provided a number of recommendations including interdisciplinary collaboration and a focus on improving the safety of medication administration.

It is evident that significant opportunities exist to improve medication safety in the hospital setting. This study will evaluate the impact of deploying pharmacists to patient care areas to reduce errors associated with medication prescribing and administration of medications in hospitalized patients.

Methodology

The proposed study would determine the number and types of medication errors intercepted by pharmacists at the prescribing and administration steps of the medication use process during the equivalent time that the pharmacists would be checking medication cassettes. Information on medication-related encounters such as drug information questions would also be collected. A baseline study will be conducted to determine the actual time spent by pharmacists checking medication cassettes and the time of day involved. During the study, data on errors intercepted and medication-related encounters will be collected during the same time period as when the pharmacists were formerly checking medication cassettes.

Pharmacists will document prescribing errors intercepted and medication-related encounters in a relational database that will include the medication involved and categorization of the error type based on methodology previously published in the scientific literature. The potential severity of intercepted errors will be determined using the National Coordinating Council on Medication Error Reporting and Prevention Taxonomy of Medication Errors (NCCMERP).[xvi] Errors intercepted and medication-related encounters associated with medication administration will be documented via a modified quality assurance form already in use by the organization for reporting of medication occurrences. This data will also be categorized by error type and medication involved as well as severity using the NCCMERP definition as

stated above. Errors intercepted and medication-related encounters documented during the study period will be evaluated to determine the following:

- Top 10 drugs involved in potential prescribing and administration errors
- Types of medication errors intercepted at the prescribing and administration steps of the medication use process and their relative frequency
- Comparison of the intercepted errors with national USP MedMARX data.[xvii]
- Factors contributing to prescribing and medication administration errors
- Potential harm that could have resulted if the error had not been intercepted

The results will be reviewed by the Vice Chair of the Pharmacy and Therapeutics Committee and the Chief Nursing Officer to validate the findings. System improvements resulting from the evaluation of errors will be identified.

Reports to the Board

Interim results of the study will be reported to the Board at the conclusion of 12 months from the start of the study. It is anticipated that the study will take place over a 2 year period. During this time, the same methodology for certification of technicians and quality assurance will be utilized as during the previous study. Documentation will be maintained on file at Cedars-Sinai Medical Center.

The assistance of Roslind Bowens, Pharm.D. in the preparation of this proposal is acknowledged.

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Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes

PETER J. AMBROSE, FRANK G. SAYA, LARRY T. LOVETT, SANDY TAN, DALE W. ADAMS, AND RITA SHANE

Abstract: The accuracy rates of board-registered pharmacy technicians and pharmacists in checking unit dose medication cassettes in the inpatient setting at two separate institutions were examined.

Cedars-Sinai Medical Center and Long Beach Memorial Medical Center, both in Los Angeles county, petitioned the California State Board of Pharmacy to approve a waiver of the California Code of Regulations to conduct an experimental program to compare the accuracy of unit dose medication cassettes checked by pharmacists with that of cassettes checked by trained, certified pharmacy technicians. The study consisted of three parts: assessing pharmacist baseline checking accuracy (Phase I), developing a technician-training program and certifying technicians who completed the didactic and practical training (Phase II), and evaluating the accuracy of certified technicians checking unit dose medication cassettes as a daily function (Phase III).

Twenty-nine pharmacists and 41 technicians (3 of whom were pharmacy interns) participated in the study. Of the technicians, all 41 successfully completed the didactic and practical training, 39 successfully completed the audits and became certified checkers, and 2 (including 1 of the interns) did not complete the certification audits because they were reassigned to another work area or had resigned. In Phase II, the observed accuracy rate and its lower confidence limit exceeded the predetermined minimum requirement of 99.8% for a certified checker. The mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The difference in mean accuracy rates between pharmacists (99.52%, 95% confidence interval [CI] 99.44–99.58%) and technicians (99.89%, 95% CI 99.87–99.90%) was significant ($p < 0.0001$).

Inpatient technicians who had been trained and certified in a closely supervised program that incorporated quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

Index terms: Administration; Dispensing; Drug distribution systems; Personnel, pharmacy; Pharmacists, hospital; Pharmacy, institutional; hospital; Professional competence

Am J Health-Syst Pharm. 2002; 59:1183–8

The rapidly changing health care environment necessitates that health care organizations optimize limited resources while improving the quality of care provided. Medication-related complications cost the American health care system as much as $177 billion annually.[1] Pharmacist expertise in drug therapy has repeatedly demonstrated improved patient outcomes, fewer complications, and better control of the cost of medication use.[2-4] However, there currently is a critical shortage of pharmacists, as documented in the Department of Health and Human Services report to Congress on the pharmacist workforce.[5] This shortage is especially acute in California, where the ratio of 58 pharmacists to 100,000 people in the population is well below the national average of 71 pharmacists to 100,000 people in the population. In this same report, the Pharmacy Manpower Project Aggregate Demand Index for California indicated a high

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Presented to the California State Board of Pharmacy, Los Angeles, CA, January 24, 2001.

level of demand for pharmacists. The current shortage of pharmacists poses a significant challenge to providing and maintaining the desired level of pharmaceutical care.[6]

The importance of pharmacy technicians in ensuring the efficient operation of hospital pharmacies is widely recognized. By reassigning nondiscretionary drug distribution tasks to pharmacy technicians, pharmacists can be redeployed to prevent adverse drug events and ensure optimal medication use. In California, unit dose medication cassettes that are filled by pharmacy technicians must be checked by a pharmacist. Pharmacists spend one hour per day checking technician-filled medication cassettes, which competes with the increasing demands on pharmacists to provide clinical services and become more involved in medication safety initiatives, in addition to dealing with the increased complexity of hospitalized patients and the pharmacist shortage. Expanding the role of technicians by implementing a structured training program with ongoing quality assurance measures may ease the impact of the pharmacist shortage through the judicious and appropriate use of skilled support personnel and increase the time available to pharmacists to perform clinical functions.

Background

In 1997, the California State Board of Pharmacy was petitioned to authorize board-registered pharmacy technicians to check unit dose cassettes filled by other pharmacy technicians in the inpatient environment. In response to strong opposition from some professional organizations and community pharmacists, who were concerned that the exemption could be expanded outside of the inpatient pharmacy environment and jeopardize pharmacist jobs, the board voted not to grant this petition. However, the board did express a desire to receive additional evidence to further evaluate allowing pharmacy technicians to perform this function. Thus, Cedars-Sinai Medical Center (CSMC) and Long Beach Memorial Medical Center (LBMMC) petitioned the board to grant a waiver of the California Code of Regulations to conduct an "experimental program" under the direction of the University of California, San Francisco, School of Pharmacy. The purpose of the program was to compare the accuracy of unit dose medication cassettes checked by pharmacists with those checked by trained, registered pharmacy technicians in the inpatient setting. In May 1998, the waiver was granted for the experimental program known as "Evaluating the Use of Board Registered Pharmacy Technicians in a Unit-Dose Drug Distribution System." The waiver was initially granted through November 1, 2000, and was extended to December 2002 on the basis of data generated from this study, which was presented to the board in January 2001.

CSMC is a 900-bed, acute tertiary care hospital in Los Angeles, California, and LBMMC is a 540-bed, acute tertiary care hospital in Long Beach, California. The unit dose drug distribution system used by CSMC and LBMMC is diagrammed in Figure 1. It should be emphasized that the process of filling and checking unit dose medication cassettes is preceded by the review and verification of all medication orders by a pharmacist. The pharmacist evaluates the appropriateness of the medication, dose, dosage form, route of administration, and frequency in the order and screens for drug allergies, drug–drug interactions, and contraindications. A pharmacist is also responsible for dispensing any initial medication doses needed before the regularly scheduled unit dose cart distribution.

Pharmacy technicians do not evaluate the accuracy and appropriateness of medication orders. Pharmacy technicians perform manipulative and nondiscretionary functions only under the supervision of pharmacists. When filling a medication cassette with unit dose medications, a technician reads a list of medications (a "fill list") previously verified by a pharmacist, removes the unit dose medication from stock, and places it in a patient's cassette or medication drawer. Next, a "checker" verifies the filled cassette against the fill list to minimize the possibility of errors before the medications are sent to the nursing areas. In California, only a pharmacist can check these unit dose cassettes, which necessitated the waiver from the board of pharmacy to allow technicians to perform this function in this program. It should be noted that nurses also check the medication when removing it from a patient's cassette and confirm it with the medication administration record (also reviewed and approved by a pharmacist) before administering the medication to the patient, in accordance with Joint Commission on Accreditation of Healthcare Organizations and California Department of Health Services requirements. Thus, a medication is triple-checked before it is administered to a patient.

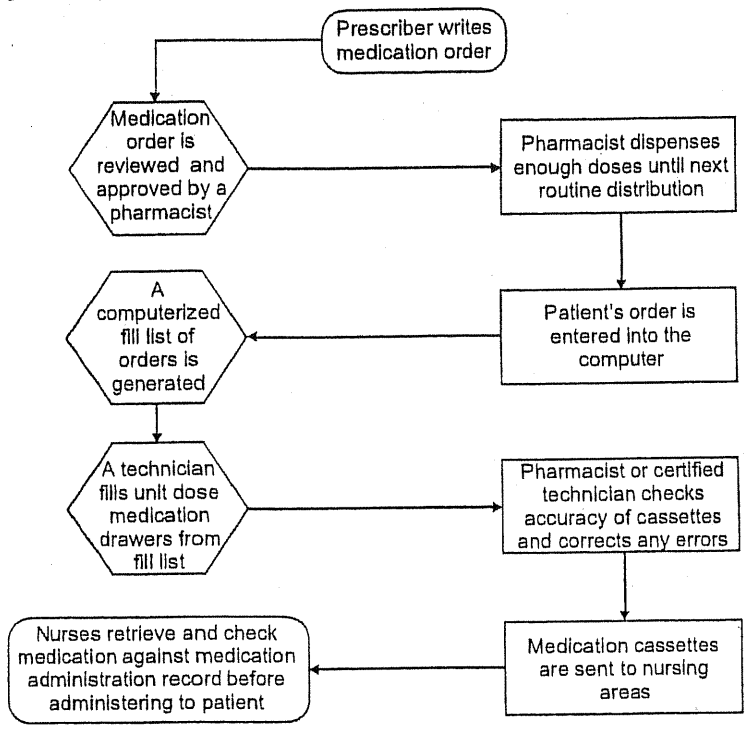
This article describes the experimental program and the accuracy of trained technicians checking unit dose medication cassettes compared with that of pharmacists.

Methods

This study was conducted concurrently at both CSMC and LBMMC and consisted of the following three phases, which were modeled from previous studies[7-13]:

- Phase I: Assessing the baseline accuracy rate of pharmacists checking unit dose medication cassettes,
- Phase II: Developing a technician training program for checking unit dose cassettes and certifying technicians who successfully completed the training program, and

Figure 1. Diagram of the inpatient unit dose drug distribution system used at both Cedars-Sinai Medical Center and Long Beach Memorial Medical Center in normal practice and during the study.



- Phase III: Evaluating the accuracy of certified technicians checking unit dose medication cassettes by conducting quality assurance audits.

Phase I began in June 1998 with the goal of auditing a minimum of 12,500 doses at each institution. Staff pharmacists checked all unit dose cassettes filled by technicians as was the pharmacists' normal routine during the day shift. They were aware that audits were being conducted. Study participants were selected on the basis of their normal work schedules, and no attempt was made to alter assignments. In addition to any spontaneous errors made by technicians filling the cassettes, artificial errors were randomly introduced by pharmacist "auditors" assigned to oversee the study process. Artificial errors were introduced at a rate of at least one error per 500 doses (0.2%) to coincide with a 99.8% minimum accuracy rate.[7] The pharmacist checkers documented and corrected any errors they detected. Subsequently, the pharmacist auditor would audit and verify the accuracy of the pharmacist checker in detecting and correcting artificial and spontaneous filling errors for all doses dispensed during the audit period. Spontaneous and artificial errors overlooked by the pharmacist checkers were documented on an audit form and corrected by the pharmacist auditors before the medication cassettes were distributed to the nursing stations. There were a total of three pharmacists at CSMC and five at LBMMC who were responsible for introducing artificial errors and auditing the pharmacists. In all three phases of the study, an error was defined as a wrong drug, dose, quantity, or dosage form; expired medication; inaccurate concentration; wrong patient's medication cassette; or missing drug.

During Phase II of the program, the pharmacy services departments at CSMC and LBMMC collaborated on a training syllabus, qualifying examination, and data collection forms. Technicians and pharmacy interns (employed and functioning as technicians) were eligible to be included in the study if they were registered with the California State Board of Pharmacy and had at least six months of experience filling unit dose medication cassettes. They were then given didactic and practical training, in accordance with the approach used by the Minnesota Society of Hospital Pharmacists in a pilot project in which technicians were trained to check unit dose cassettes filled by other technicians.[7] The didactic component consisted of lectures on the unit dose process, proper packaging and repackaging techniques, medication safety, and basic pharmaceutical calculations. The didactic training concluded with an examination. Technicians were required to achieve a minimum passing score of 80% on the examination. The practical training included observing a pharmacist checking unit dose cassettes and actual hands-on experience. After successful completion of the didactic and practical training, the technicians were audited for accuracy in checking unit dose cassettes for at least 3500 consecutive doses. Artificial errors, as described for Phase I of the program, were also introduced in this process. The audits were conducted by the same pharmacist auditors as in Phase I. To become a certified technician checker in this program, an overall accuracy rate of at least 99.8% was required. This phase of the study began in June 1998 and was continued as new technicians were trained and included in the program.

Phase III began in April 1999. In this phase, certified technician checkers were responsible for checking unit dose medication cassettes as a daily activity while under the supervision of a pharmacist. Monthly quality assurance audits of at least 500 doses were conducted for each certified technician checker, using

the same procedure of introducing random artificial errors as previously described. Accuracy was to be maintained at 99.8% or higher. If a certified technician checker failed a monthly audit, the audit was to be repeated within 30 days. If the technician failed the second audit, the technician would be removed from the checking position until he or she was retrained and recertified. If a certified technician checker did not perform this function for more than three months, an audit would be conducted when the technician restarted checking medication cassettes. If a technician had not checked cassettes for more than six months, recertification was required.

In January 2000, the board approved the following requested amendment to the program: "In Phase III of the study, a monthly audit will be conducted for 3 months, and if the accuracy rate meets or exceeds the minimum target of 99.8% for three consecutive audits, future audits will be conducted quarterly thereafter for that technician. Technicians failing a quarterly audit will have to pass three consecutive monthly audits before resuming quarterly audits." The amendment had been requested by CSMC and LBMMC, since no certified technician had failed a monthly audit.

Error rates were calculated as the number of errors discovered by the auditors divided by the total number of unit doses audited. The accuracy rate was defined as one minus the error rate, which was then converted to a percentage. The 95% confidence intervals for these rates and p values for comparing the pharmacist and technician checkers were computed using SAS, version 6.12 (SAS Institute, Cary, NC). An additional analysis was conducted to ensure that wide variation in accuracy rates among individual technicians did not exist, since this could result in a favorable mean accuracy rate and mask the performance of one or more technicians who performed below the established goal of 99.8%. Mixed-effects logistic regression models with a random-checker effect were used to confirm the results.

Results

Twenty-nine pharmacists (15 at CSMC, 14 at LBMMC) participated in Phase I of the study to supply baseline data of the checking accuracy of pharmacists. A total of 41 technicians (24 at CSMC, 16 at LBMMC, and 1 working at both), three of whom were interns, participated in Phase II of the study. All 41 technicians successfully completed the didactic training, 39 successfully completed the audits and became certified checkers for Phase III, and 2 technicians (including 1 of the interns) did not complete the certification audits because they were reassigned or had resigned.

Table 1 lists the combined-institution accuracy rates of pharmacist and technician checkers in Phase I and II, respectively. For technicians, both the observed average accuracy rate and its lower confidence limit exceeded the minimum requirement of 99.8% for a certified checker. The difference in accuracy rates between pharmacists and technicians was significant ($p < 0.0001$). Interestingly, the mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The two pharmacy interns had accuracy rates of 99.89% and 99.97%. One technician had an accuracy rate of 99.75%, which was just below the target rate, and subsequently met the minimum requirement and became certified after the next audit.

In Phase III, all certified technicians at both institutions maintained a minimum accuracy of 99.8% during their monthly and quarterly audits. Phase III began in April 1999; through December 2001, no certified technician checker had failed any quality assurance audits. However, some technicians were removed from the list of certified checkers during the study period because of work reassignments or other non-study-related issues. The board of pharmacy was continually updated on the names of certified technician checkers in the semiannual reports submitted.

Discussion

The proposition of allowing trained technicians to check unit dose medication cassettes filled by other technicians has been hotly debated in California in the past decade (appendix). This study's results appear to support the ability of well-trained technicians to accurately check unit dose medications.

Several studies have been published evaluating the accuracy of pharmacy technicians in checking other technicians in a unit dose medication fill system.[7-13] Our results corroborate the findings from these studies; in fact, we observed a higher accuracy rate for technicians than for pharmacists ($p < 0.0001$). The boards of pharmacy in Kansas, Minnesota, and Washington currently allow technicians to check unit dose medication cassettes filled by other technicians. In addition, the American Society of Health-System Pharmacists and the

Table 1.
Accuracy of Pharmacists and Technicians in Checking Unit Dose Medication Cassettes

Checker	No. Participants	No. Doses Checked	Mean Accuracy Rate (%)[a]	95% Confidence Interval (%)
Pharmacists	29	35,829	99.52	99.44–99.58
Technicians[b]	39	161,740	99.89	99.87–99.90

[a] The difference in accuracy rates between pharmacists and technicians is significant ($p < 0.0001$), using mixed-effects logistic regression models.
[b] Includes two pharmacy interns who were employed and functioning as technicians.

California Society of Health-System Pharmacists (professional policy 9801, October 1998) support the role of the technician in checking unit dose medication cassettes.

The expansion of the technician's role has been shown to increase pharmacists' productivity.[14] We estimated that pharmacists at each institution spent approximately one hour per day per pharmacist checking unit dose medication cassettes before the program was implemented. In this experimental program, the pharmacists were able to use this additional time to expand clinical services and respond to drug therapy-related requests from physicians, such as dosing recommendations. The training and auditing of technicians for checking medication cassettes are centralized and carried out by the technician supervisor, who is under the direction of a pharmacist manager. By centralizing this responsibility, decentralized pharmacists gain additional time for direct patient care activities. Also, pharmacists at both institutions have reported an increase in job satisfaction after implementing the experimental program.

When evaluating the study results, some limitations should be acknowledged. The pharmacist checkers selected to determine the baseline accuracy rate of checking unit dose medication cassettes were those who happened to be staffing the inpatient areas on the dates that the audits were performed. Neither the pharmacist checkers nor the dates of the audits were randomized. The pharmacists and the technicians were cognizant of the study, although they did not necessarily know when audits were to be conducted. Artificial errors introduced were not randomized using a random numbers table but were based on the judgment of the pharmacist auditors who attempted to introduce a variety of different errors. The auditors at each institution introduced errors independently. In addition, the severity of errors was not defined in the study; therefore, this information was not included in the results.

The results of this study were presented to the California State Board of Pharmacy, which is now reconsidering allowing technicians to check unit dose cassettes filled by other technicians in the inpatient setting, under the same conditions of this study. The waiver for this study expires in December 2002. Until state regulations are changed or the expiration date is reached, both institutions will continue to gather data from the quarterly audits.

Conclusion

In this study, we concluded that pharmacy technicians who had been trained and certified in a closely supervised program that incorporates quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

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Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians

Year	State Regulation
Before 1993	Acute care hospitals in California were permitted to allow technicians to check the accuracy of technician-filled inpatient unit dose medication cassettes, under chart order exemption in the pharmacy regulations.
1993	The use of inpatient pharmacy technicians to check technicians filling unit dose cassettes was deemed unacceptable by the California State Board of Pharmacy, as evidenced by the following correspondence provided to the California Association of Hospital and Health Systems: "Please note the law does not authorize a technician to check another technician. While a technician may check another technician, the final check must always be done by a pharmacist."

Continued on next page

Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians *(continued)*

Year	State Regulation
1994	The Hospital Pharmacy Committee of the California State Board of Pharmacy proposed draft language to add a section to the California Code of Regulation (CCR1717) to allow pharmacy technicians to check the work of other pharmacy technicians in connection with filling unit dose medication cassettes for patients whose orders had been previously reviewed by a pharmacist.
1995	This draft language was presented in May at a board of pharmacy informational hearing.
1996	In June, as a result of failure to reach agreement over the proposed language, the board developed a technician committee. This committee was charged to evaluate the entire pharmacy technician program including changes necessary to improve the program, discuss and plan for future changes and roles of technicians, and pursue any statute or regulatory changes necessary to accommodate these practices. The committee, in an October report to the board, recommended several potential changes including asking the board to consider allowing technicians to check the work of other technicians for unit dose medication cassette filling under a waiver system that included specific provisions (e.g., functions). In response to this report, the board of pharmacy voted to move forward with regulatory action to allow technicians to check the accuracy of technicians' work in a unit dose medication cassette fill system. During this time, the board of pharmacy began to enforce the California Code of Regulations relating to the use of technicians for checking of unit dose medication cassettes and required facilities to discontinue the practice.
1997	In May, responding to requests from multiple health systems and the California Society of Health-System Pharmacists, the board of pharmacy gave notice of its intent to amend regulations to allow technician checking of technician-filled unit dose medication cassettes. All interested parties were provided an opportunity to provide oral testimony at the proposal hearing in July. At that time, the board of pharmacy did not approve moving forward with the amended regulations. In response to the many delays in reaching consensus to change current regulations, representatives from LBMMC and CSMC developed the proposal in collaboration with the University of California, San Francisco, School of Pharmacy to perform a study in order to provide the board with objective data.
1998	On May 27, the board granted the requested waiver of the California Code of Regulations to conduct the "experimental program." The waiver was initially granted until November 1, 2000. However, the waiver was subsequently extended until February 1, 2001.
2001	In January, having reviewed the results of this study, the board extended the waiver until December 2002.

ly, and their disability cannot limit their access to equal health care services.[2,3] Current pharmacy practice legislation and pharmacy reimbursement restrictions in New York, as highlighted by this case, limit the ability of pharmacists to meet the needs of patients receiving home care.

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3. *Olmstead* v. *L.C.*, 138 F.3d 893(U.S. Supreme Court 1999 June 22).

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Correction

Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes (June 15, 2002, Report). On page 1185, the caption for Figure 1 should read, "Diagram of the inpatient unit dose drug distribution system used at both Cedars-Sinai Medical Center and Long Beach Memorial Medical Center in normal practice and during the study. Certified technicians can only check unit dose cassettes under the waiver by the California Board of Pharmacy. Medication administration records are verified by pharmacists before used by nurses."

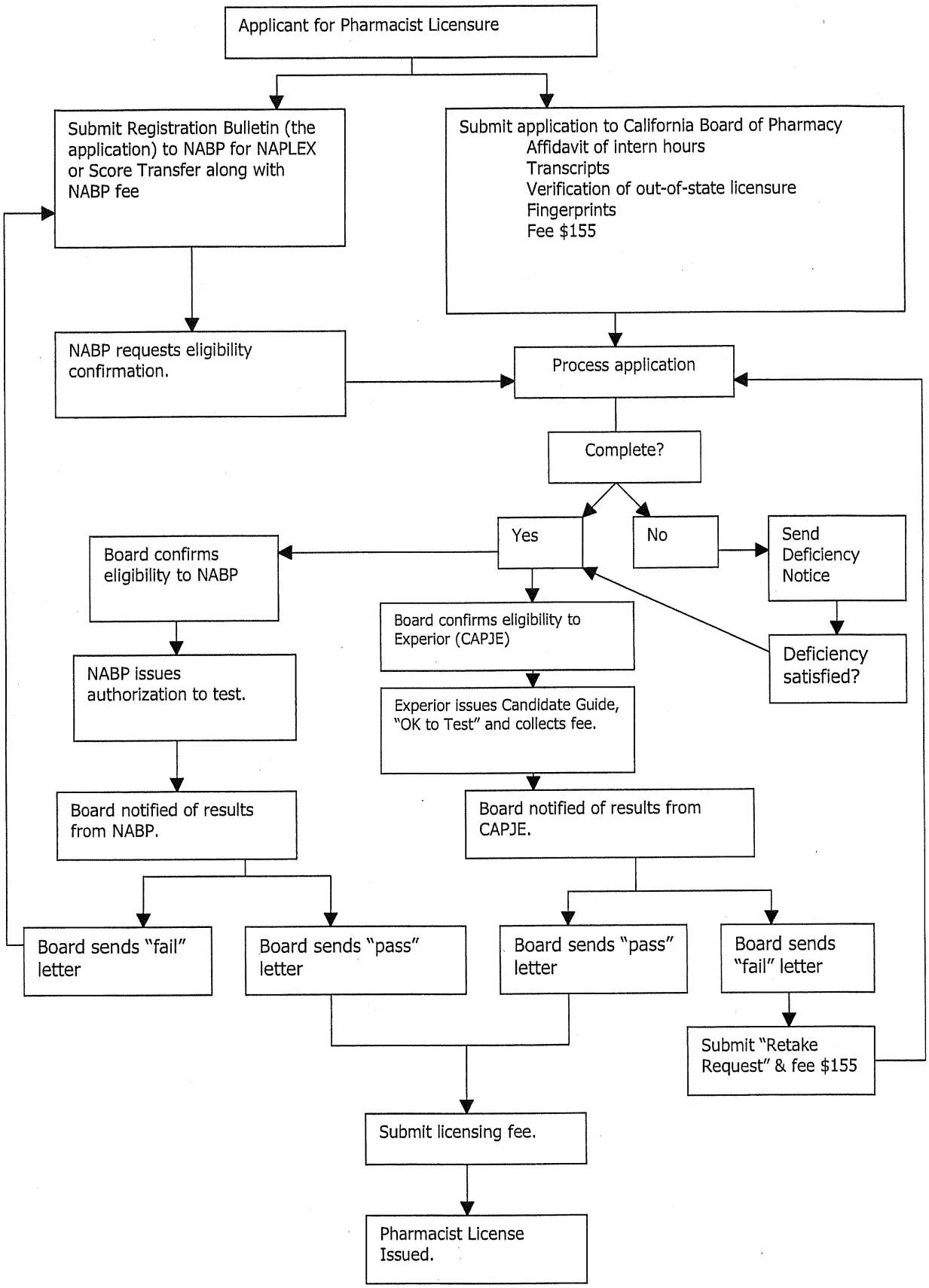
ATTACHMENT G

Board of Pharmacy
Draft Amendment to Section 4207
Application Investigation

Amend Section 4207 of the Business and Professions Code, to read:

4207. (a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant ~~and the premises for which a license is applied qualify~~ is qualified for the ~~for a~~ license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.
(b) The board shall not~~, however,~~ investigate any matters connected with the operation of a premises~~, including operating hours, parking availability, or operating noise,~~ other than those matters solely related to the furnishing of dangerous drugs and dangerous devices that~~, solely due to the furnishing, sale, or dispensing of narcotics, dangerous drugs, or dangerous devices~~ might adversely affect the public welfare.
(c) The board shall deny an application for a license if ~~either~~ the applicant ~~or the premises for which a license is applied do~~ does not qualify for the license being sought. ~~a license under this article.~~
(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act.

ATTACHMENT H



Revised 11/21/2003

California Board of Pharmacy

CALIFORNIA PHARMACY JURISPRUDENCE EXAMINATION HANDBOOK

Effective March 1, 2004

CONTENTS

FOR MORE INFORMATION

All questions and comments about the testing process should be directed to:

Experior
1260 Energy Lane
St. Paul, MN 55108
Voice: 800.894.9962
TDD User: 800.790.3926
Web site: www.experioronline.com

Questions about examination content should be directed to:

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814
916.445.5014
Web site: www.pharmacy.ca.gov

GENERAL GUIDELINES AND INFORMATION

Introduction and Purpose of Handbook

This handbook provides candidates with important information regarding the California Pharmacist Jurisprudence Examination (CPJE), one of two examinations required for licensure as a pharmacist in California [the other is the North American Pharmacist Licensure Examination (or NAPLEX), which is administered by the National Association of Boards of Pharmacy]. For information on the NAPLEX, go to www.nabp.net.

The board strongly recommends that candidates thoroughly read and study from this handbook to prepare for the examination. This handbook describes in detail what to expect upon arrival at the examination site. It also provides recommendations for study, information on the format of the examination and examples of test questions candidates will encounter on the examination. It provides information about how and when exam scores are released, and what to do after the results are received.

Objectives of the California State Board of Pharmacy

The California State Board of Pharmacy is a consumer protection agency. One way the board fulfills its consumer protection mandate is to assure that those licensed to practice pharmacy possess minimum competency. To this end, California law requires candidates to take the NAPLEX and a California-specific examination (California Business and Professions Code section 4200). You can obtain a copy of this code and other California pharmacy laws from the board's Web site. These examinations require candidates to demonstrate that they possess the minimum knowledge and abilities necessary to perform safely and effectively in independent pharmacy practice in the U.S. as well as in California.

Information about the NAPLEX must be obtained from the National Association of Boards of Pharmacy (contact www.nabp.net), which prepares its own Registration Bulletin about the examination. The remainder of this handbook will focus on the California-specific examination, the CPJE.

THE EXAMINATION PROCESS

Apply to the Board of Pharmacy

Before you can take the CPJE, the California State Board of Pharmacy must determine you are qualified to take the pharmacist licensure examination. There is an application and fee of $155 that you must submit to the board to initiate the process.

The major qualifications are that you must:

- have obtained a B.S. in Pharmacy or a Pharm.D. degree from an ACPE-accredited college of pharmacy program, or have graduated from a college of pharmacy program outside the U.S. **and** have passed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) and earned a score of at least 50 on the Test of Spoken English (TSE); and
- have completed 1,000 intern experience hours or verified licensure as a pharmacist in another state for at least one year.

For complete requirements or an application and instructions to become eligible to take the pharmacist licensure examinations in California, see the board's Web site (www.pharmacy.ca.gov).

[Note: if you are applying to take the NAPLEX with California as your primary state, the board's determination that you qualify to take the pharmacist licensure examination in California is also accepted by the NABP to be admitted to the NAPLEX. Alternatively, you may take the NAPLEX before applying to California if you use another state as your qualifying state. However, you will not be able to take the CPJE until you submit a pharmacist license and examination application to the California State Board of Pharmacy. Complete instructions on this process are available on the board's Web site in the application material for a pharmacist license.]

California will evaluate your application and all supporting documents to determine your eligibility to take the examination. You will be notified in writing of any deficiencies in the application.

If the board determines you are qualified, you will receive a written notification from the board. The board will simultaneously notify Experior Assessments and NABP that you have been determined eligible. Then wait one week for Experior to mail you a handbook – do not contact them before you receive the handbook, unless it has been three weeks since you received your eligibility determination letter from the board. Experior will mail you a handbook (this handbook), the back cover of which will provide you with your Notice of Eligibility for the CPJE.

Experior Assessments — Test Provider of the CPJE

The California State Board of Pharmacy has contracted with Experior Assessments, LLC (Experior) of St. Paul, Minn., to administer the CPJE. The CPJE is administered at a computer, according to a pre-scheduled appointment.

Pharmacist candidates who have been designated by the board as "eligible" to take the CPJE, may take the examination at any of Experior's 125 administration facilities across the United States. To identify the locations of these test sites, call Experior at 800.894.9962 or go to their Web site (www.experioronline.com). Maps and directions to the California testing centers begin on Page 12 of this handbook. The process for scheduling an examination is described below.

Questions about testing centers or scheduling an appointment to take the CPJE should be directed to:

Experior
1260 Energy Lane
St. Paul, MN 55108
Voice: 800.894.9962
TDD User: 800.790.3926

Examination Registration

When you are mailed this handbook, you have been determined as eligible to take the examination. You must register for the examination and pay the $40 test administration fee to Experior, then schedule an appointment to take your examination. You may choose to use the Internet, phone or mail; each method is described in the following sections.

REGISTRATION AND PAYMENT BY INTERNET

You may register, pay your administration fee and schedule your examination online anytime after you have received your notice of eligibility using our Internet Registration and Scheduling Service at www.experioronline.com. To use this service on our Web site, follow these easy steps:

- Go to *www.experioronline.com* and select *Other*.
- Choose *California* from the list of states provided.
- Select *Board of Pharmacy*.
- Click on *Online Registration and Scheduling Services* to create your own user ID and password.
- Follow the simple, step-by-step instructions to complete the registration process.
- Complete the process by scheduling your examination appointment online.

If you require testing accommodations, please see *Special Test Considerations* on Page 4.

REGISTRATION AND PAYMENT BY TELEPHONE

You may also choose to register, pay your administration fee and schedule an exam appointment in one phone call to 800.894.9962. Please have your credit card information ready when you call.

REGISTRATION AND PAYMENT BY MAIL

You may mail your registration form, found on Page 15 of this handbook and $40 payment to Experior and it will be processed within 48 hours from the time it is received. (Please allow four to eight days for mail delivery.) You may pay by including a MasterCard or Visa number, money order, business check or cashier's check. PERSONAL CHECKS AND/OR CASH ARE NOT ACCEPTED, AND REGISTRATIONS RECEIVED VIA EXPRESS DELIVERY ARE NOT PROCESSED MORE QUICKLY THAN THOSE RECEIVED BY REGULAR DELIVERY METHODS.

If you register for your examination by mail, you must then call to schedule your examination appointment (see *Appointments and Cancellations* below for details).

Scheduling the CPJE

APPOINTMENTS

If you choose not to register and schedule in one easy step using the Internet or telephone, you will need to schedule your appointment. After you have mailed your payment to Experior, you must arrange the time and place for taking your examination by calling Experior at 800.894.9962 between 5 a.m. and 6 p.m. Pacific Standard Time, Monday through Friday.

You may take the CPJE at any Experior testing center in the United States. There are approximately 125 of these testing centers nationally. The eight locations in California are printed at the back of this handbook. The other national test centers can be obtained from Experior's Web site or by contacting Experior.

Appointments are available six days per week at most centers. Schedule your test early to get your preferred site and time, preferably within 90 days from the date of your notice of eligibility.

For time-planning purposes, you will have two hours maximum to take the examination. In addition, there is an orientation session immediately before you start the CPJE to familiarize you with the computer's use. This orientation time will not count as part of the two-hour period allocated for the CPJE.

Consider confirming your scheduled test by calling Experior several days before your examination.

There is no testing on the following holidays or weekends on which the holiday falls:

- New Year's Day
- Martin Luther King Jr. Day
- President's Day
- Memorial Day
- Independence Day
- Labor Day
- Thanksgiving & Friday After
- Christmas Eve, Day & Monday After

RESCHEDULING YOUR APPOINTMENT

To change your appointment time, you must call Experior. There must be at least **three full working days** between the day of your call and the day of your appointment. **Before you call to reschedule, please refer to the chart below. If you reschedule without giving three full business days notice, you WILL forfeit your $40 administration fee.**

Please note: the schedule below does not include holidays.

If your exam is on:	Call by 6 p.m. Pacific time the previous:
Monday	Tuesday
Tuesday	Wednesday
Wednesday	Thursday
Thursday	Friday
Friday	Monday

CANCELING YOUR APPOINTMENT

If you cancel your appointment less than three working days before the date of your scheduled examination, you will forfeit your $40 fee. To reschedule another examination date, you will need to pay another $40 administration fee directly to Experior.

EXPIRATION OF EXAMINATION ELIGIBILITY

Your examination eligibility expires and your application is deemed abandoned if your fail to take the CPJE within one year after being notified of your eligibility by the board.

When your eligibility expires, you will need to reapply to the board to be considered eligible to take the examination. To reapply, use the application for Pharmacist Licensure and Examination, which can be downloaded from the board's Web site.

When your eligibility expires, you will need to reapply to the board to be considered eligible to take the examination using the application for pharmacist licensure and examination.

EMERGENCY CLOSURE OF TESTING CENTERS

In the event of an emergency, Experior may need to cancel scheduled examinations. In this situation, Experior personnel will attempt to contact you via telephone; however, you may confirm your scheduled test by calling Experior at 800.894.9962. If a site is closed, exams will be rescheduled at your earliest convenience, at no cost to you. To reschedule your examination, call the toll-free number.

Taking the Examination

Your examination will be given at a computer station at an Experior testing center.

You should arrive at least 15 minutes before your scheduled appointment to allow time for you to sign in, verify your identification and have Experior take your photograph.

You will have a maximum of two hours to take the examination.

You do not need any computer experience or typing skills. You will have a personalized introduction to the testing system and an introductory lesson (tutorial) on the computer before you start your test. The time you spend in the tutorial does not count toward your examination time.

Experior's Web site provides a demonstration of Experior's computer-based testing system. The demonstration is intended to give candidates an idea of the look and feel of the examination screens. It is not intended to be a study tool. To view the demonstration, go to www.experioronline.com and click on "other," then choose "California." Click "CBT Demo" on the right-hand side of the screen.

During the examination, should you experience any disruption or difficulty, it is your responsibility to notify a proctor immediately so that the situation may be resolved whenever possible.

What to Bring to the Testing Center

You must bring specific forms of identification with you to be admitted into the test site. Your identification must include both of the following:

- a government-issued identification (driver's license, state-issued identification card, military identification) containing a recent photograph of you; AND
- your federal Social Security card.

The name appearing on both of these identification cards must match exactly the name used to register you for the CPJE (the name on the back of this handbook), including designations such as "Jr." or "III," etc.).

If you do not have appropriate identification with you when you arrive at the test center, you will not be admitted to take the examination, and Experior will consider this a missed appointment. If this occurs, you will need to pay another $40 to reschedule another examination.

If you cannot provide the identification listed above, contact Experior before scheduling your appointment to arrange for an alternative form of meeting this requirement.

If you have reported a name change to the board, after your eligibility was transmitted to Experior, ensure the name on your identification matches Experior's record (as it appears on this handbook) before your examination.

What NOT to Bring to the Testing Center

At the test facility, you may not bring the following items inside the testing room:

- Personal belongings, including: purses, wallets, watches, stopwatches, clocks, backpacks, books, study notes, writing tools, cameras, tape recorders, pagers, palm pilots, calculators, cellular phones.
- Medications.
- Food, candy or drinks.

If you do bring such items with you to the test site, Experior will provide accordion folders for storage of your belongings in the reception area. If you need to take a break during the exam, you may access some types of secured belongings under the supervision of a test administrator. Only those items that are deemed appropriate for the purpose of the break may be removed from the accordion folder. Access to such items as wallets, backpacks, books, study notes, writing tools, cameras, tape recorders, pagers, palm pilots, cellular phones, watches, stopwatches, and clocks during breaks will be strictly prohibited. Experior will not be responsible for items left in the reception area.

No guests, visitors or family members are allowed in the testing or reception areas.

Failure to follow these procedures may result in the disqualification of your examination

Note: You will be provided with notepaper and a pencil at the test site so that you can take notes or make calculations needed for the examination. This paper will be picked up from you after the examination.

There are timing mechanisms available at the test site to help you keep track of your time during the two hours of test administration.

Complaints Regarding Test Administration

Experior's goal is to provide a comfortable and professional testing experience for every examinee. If a disruption or problem occurs that you believe will substantially impact the outcome of your examination, you must document your concerns on the exit survey at the end of your examination.

The exit survey is also a means for you to provide constructive feedback regarding your examination experience and/or comments on examination content. These comments are shared with the board's Competency Committee.

Examination Security

The board, Department of Consumer Affairs and Experior Assessments are committed to maintaining the security and the confidentiality of all examination materials during every phase of development, implementation and storage. If you violate any security procedure, the board may, among other options: delay your results; void your examination score; cancel your intern pharmacist permit; deny your application as a pharmacist; deny you admission to future examinations.

Experior reserves the right to videotape any examination session.

As part of the board's application for the pharmacist licensure examination, you are required to sign a security agreement. When you sign this agreement, you are affirming that you fully understand that you are responsible for upholding examination security in accordance with California Business and Professions Code section 496. In accordance with the law, a violation of any of the rules listed below will result in your disqualification as a candidate and could result in an administrative action and/or denial of a pharmacist or intern pharmacist license by the board.

Candidates are neither permitted to discuss the content of the examination nor remove any examination materials from the testing sites at any time. All examination materials are confidential.

As a candidate taking the CPJE, you are required to follow the provisions of Business and Professions Code sections 123 and 584. You are not allowed to:

- have an impersonator take the examination on your behalf;
- impersonate another person to take the examination on that person's behalf;
- communicate examination content with another examinee or with any person other than the staff of the California State Board of Pharmacy
- reproduce or make notes of examination materials and/or content and reveal them others who are preparing to take the examination or to those who are preparing other candidates to take the examination; and
- obstruct the administration of the examination in any way.

Special Test Considerations

ACCESSIBILITY OF TESTING CENTERS

All examination sites are physically accessible to individuals with disabilities. Scheduling services are also available via Experior's Telecommunications Device for the Deaf (TDD) by calling 800.790.3926.

EXAMINATION ACCOMMODATIONS

The board and Experior recognize their responsibilities under the federal Americans with Disabilities Act and the California Fair Employment and Housing Act by providing testing accommodations or auxiliary aids or services for candidates who substantiate the need due to a physical or mental disability or qualified medical condition. Requests for testing accommodation must be received by the board a minimum of 90 days before the test date to allow for processing. Accommodations that fundamentally alter the measurement of the skills or knowledge the examination is intended to test will not be provided.

REQUESTING EXAMINATION ACCOMMODATIONS

Accommodations will not be provided at the examination site unless prior approval by the board has been granted.

Reasonable, appropriate, and effective accommodations may be requested from the board by submitting the "Request for Accommodation of Disabilities" package, which can be obtained from the board's Web site (www.pharamcy.ca.gov).

Do not call Experior to schedule your examination until you have received written notification from the board regarding your request for accommodations.

ADMINISTRATION OF THE CPJE

Composition and Test-Taking Strategies

The board's CPJE is comprised of 90 multiple-choice questions, administered on a computer at designated test locations throughout the country. Once the board has determined that you are eligible to take the examination, you will select the location and day and time of your examination.

You will have two hours to complete the examination. If you need to take a restroom break during the examination, you will not receive additional time to complete the test.

Of the 90 multiple-choice questions on the examination, 75 questions are test questions that will be scored and 15 questions are pretest items. The 15 pretest questions will not be counted for or against you in your score. Pretesting questions allows the board to gather performance data and evaluate the questions before they become scoreable in a future examination. These pretest questions will be distributed throughout the examination, and will NOT be identified as pretest items.

All of the questions on the examination have been written and reviewed by the board's Competency Committee. Each question is based on a job-related task and knowledge statement contained in the examination's Content Outline.

When taking the examination, you should remember the following two points:

- There is only one answer for each question.
- Since scores on the examination are based on the number of correct answers, there is no penalty for guessing. It is to your advantage to answer every question.

Occasionally, candidates may encounter questions that they believe are ambiguous. When this occurs, record your comments on the comment form that you will be given at the test site. This information will be provided to the Competency Committee for review of the performance of the examination. The committee takes these comments seriously.

Candidate Notice of Exam Completion

After completing the examination, you will be provided with a Candidate Notice of Exam Completion examinee report letter, which serves as your receipt that you have completed the examination. The examinee report letter will contain your name, address, the date and location you took the examination and your picture. The board will be provided with a copy of this document.

Test Results

About 30 days after you take the CPJE examination, the board will mail your score to you at the address on your Candidate Notice of Exam Completion. Please do not call the board's office as results will not be given over the telephone. Moreover, each call delays the processing of the examination and the mailing of results.

If you pass the examination, the letter will advise you what additional items you need to become licensed as a pharmacist in California.

If you fail the CPJE, the board will give you instructions for retaking this examination. You will be required to submit a retake application to the board as part of this process.

Also, if you fail the examination, you will be provided with a score report that will provide information about your performance on the three portions of the examination (Provide Medication to Patients in Compliance with California Law,

Monitor, Communicate and Manage Patient Outcomes, Manage Operations in Accordance with California Law – see the content outline for the examination on Pages 8 and 9). This report can help you study for future examinations.

Failing the Examination Four Times

If you fail the board's licensure examination four times, you are required to take 16 semester units of education in pharmacy before you will be eligible to retake the California-required examinations. This coursework must be taken in a school of pharmacy approved by the Accreditation Council for Pharmacy Education (which until mid-2003 was known as the American Council on Pharmaceutical Education) or approved by the board.

Prior to January 1, 2004, applicants for licensure as a pharmacist took a two-part multiple choice and short-answer essay examination developed by the California board (pre-2004 version). After January 1, 2004, the board requires passage of both the CPJE and the NAPLEX to become licensed as a pharmacist (current exam structure).

When counting four failed attempts at the examination (California Business and Professions Code section 4200.1), the board uses the following criteria:

- Applicants who failed the prior examination (pre-2004 version) will have these failed attempts continue to count as failed examinations; the 2004 changes will not restart applicants to zero attempts at the pharmacist licensure examination.
- Applicants who fail the pharmacist exam after January 1, 2004, will have each attempt at the NAPLEX and the CPJE count separately as an attempt. For an applicant who has not taken the California examination before, he or she will have four attempts to pass the CPJE and four attempts to pass the NAPLEX after January 1, 2004.

Examples: Jeff took the California examination in January 2003 and June 2003, and failed both exams. Jeff will have two chances to pass the NAPLEX and two chances to pass the CPJE before he will reach four failed attempts to pass the California exam.

Lisa took the California examination in June 1998 and failed it. Lisa will have three chances to pass the CPJE and three chances to pass the NAPLEX after January 1, 2004, before she will reach the four failed attempts.

Mia took the California examination in June 1998 and failed it. Mia took the NAPLEX in February 2004 and failed it. Mia will have three chances to pass the CPJE and two chances to pass the NAPLEX.

Leonard took the California examination in June 1998 and failed it. He took the NAPLEX in November 2002 and failed it. Leonard will have three chances to pass the CPJE and three chances to pass the NAPLEX (because he took the NAPLEX before January 1, 2004, not after this date).

CALIFORNIA PHARMACIST JURISPRUDENCE EXAMINATION (CPJE)

The board's CPJE is comprised of 90 multiple-choice questions, administered by computers at designated test locations throughout the country. Once the board has determined that you are eligible to take the pharmacist licensure examination, you will be able to select the location, day and time of your examination.

California law (California Business and Professions Code section 4200.2) requires that the California-specific exam include items that demonstrate proficiency in patient-communication skills, aspects of pharmacy practice and the application of clinical knowledge that is not measured by NAPLEX and California law.

Occupational Analysis

The development of any examination program involving licensure begins with an occupational analysis, which is a method for identifying the tasks performed in a profession or a job, and the knowledge, skills and abilities required to perform that job. The purpose is to describe the activities of the profession in sufficient detail to provide a basis for the development of a professional, job-related licensing examination. The Department of Consumer Affairs' Examination Validation Policy requires that an occupational analysis be performed every three to seven years.

The board completed its most recent job analysis of pharmacists in early 2000. To do this, a job analysis advisory committee was appointed by the board to identify the activities and responsibilities of the California pharmacist and to develop the test specifications. All advisory committee members were also members of the board's Competency Committee, who oversee development of the pharmacist examination. The diversity of this advisory group was reflective of the pharmacy profession.

The analysis began with a review of the existing detailed content outline for the pharmacist licensure examination, which had been developed during the last job analysis in 1994. Additions and deletions were made to this list, which was developed into a questionnaire. Next the committee approved the rating scales that were used in the survey. Before distribution of the questionnaire to practitioners, a pilot study of a small group of California practicing pharmacists was conducted. The survey questionnaire was revised and finalized. The final survey questionnaire was

distributed to 2,000 California-residing licensed pharmacists according to a sample plan.

After the survey data was collected and analyzed, the board's Competency Committee reviewed the results. They then developed the content of the new examination plan based on the task statements and knowledge areas determined by the surveyed pharmacists as critical to practice. This selection resulted in a content outline, which was used to develop the California pharmacist licensure examinations from June 2000 through 2003.

In 2003, the Competency Committee, in response to legislation enacted by the California Legislature (SB 361, Figueroa, Chapter 539), reviewed and modified the content outline for the pharmacist licensure examination. The new law, which took effect on January 1, 2004, established two examinations to assess the knowledge of pharmacist applicants – the NAPLEX and the CPJE. The modifications to the content outline were made to assure that the full examination program for California would be job related and not duplicative. Tasks that were included in the NAPLEX content outline were removed from the California Exam's content outline (because they would be tested on the NAPLEX). The remaining tasks were combined with task statements required by the new law for the California Exam that were retained from the prior content outline (specifically to assess candidates' proficiency in patient communication skills and contemporary standards of practice for pharmacists in California). These were blended into a new content outline for the CPJE. A copy of this content outline is provided in this handbook on Pages 8 and 9.

Development of the CPJE

ROLE OF THE COMPETENCY COMMITTEE

The California State Board of Pharmacy, through its Competency Committee, develops the CPJE. The committee is comprised of pharmacists from a cross section of professional practice and each of California's schools of pharmacy. Competency Committee members are appointed by the board's president. The committee is led in examination development by a contracted psychometric consulting firm, which is hired for expertise in test validation and development and whose staff is educated and experienced in developing and analyzing occupational licensing examinations.

CRITERION-REFERENCED CUT SCORE FOR PASSING

To establish pass/fail standards for the California Exam, a criterion-referenced passing score methodology is used. The intent of this methodology is to differentiate between a qualified and unqualified licensure candidate. The passing score is based on a minimum competence criterion that is defined in terms of the actual behaviors that qualified pharmacists would perform if they possessed the knowledge necessary to perform job activities.

During a criterion-referenced passing score procedure, the Competency Committee also considers other factors that would contribute to minimum competence such as prerequisite qualifications (e.g., education, training and experience), the difficulty of the issues addressed in each multiple-choice item, and public health and safety issues. By adopting a criterion-referenced passing score, the board applies the same minimum competence standards to all licensure candidates. Because each version of the examination varies in difficulty, an important advantage of this methodology is that the passing score can be modified to reflect subtle differences in difficulty from one examination to another, providing safeguards to both the candidate and the public.

CONTENT OUTLINE

Overview

The CPJE is comprised of multiple-choice questions that:

1. Demonstrate the candidate's proficiency in patient communication skills.
2. Examine aspects of contemporary standards of practice for pharmacists in California, including pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the NAPLEX.
3. Evaluate a candidate's knowledge of applicable state laws and regulations.

Applicants should review the content outline carefully to obtain a reasonable expectation of the different topics for which they will be responsible, and to identify areas for which focused review may be helpful.

Specific references you may want to use for study include California Pharmacy Law, prior issues of the board's newsletter, *The Script*, and board-published monographs on drug therapy, *Health Notes*. You can obtain copies of California Pharmacy Law, *The Script* and *Health Notes* from the board's Web site (www.pharmacy.ca.gov). You can also purchase a Pharmacy Law handbook by using the directions on the Web site.

Questions are practice-based and are often written in a format that presents a situation, and then asks the candidate to make an appropriate decision or determination based on law.

Examination preparation courses are not necessary for success in the examination and are not a substitute for education and experience. The board does not supply examination preparation providers with confidential exam material. Additionally it is a violation of California law for candidates to provide information regarding examination content to anyone, and the board may take disciplinary action against anyone it finds has compromised the examination.

California State Board of Pharmacy

California Pharmacist Jurisprudence Exam

Detailed Content Outline

1. Provide Medication to Patients in Compliance with California Law (29 Percent)

A.	***Organize and Evaluate Information as Communicated by the Prescriber, Prescriber's Authorized Agent, or Patient/Patient's Representative***	
	1.	Assess prescription/medication order for completeness, correctness, authenticity, and legality
	2.	Assess prescription/medication order for reimbursement eligibility
	3.	Evaluate the pharmaceutical information needs of the patient/patient's representative
B.	***Dispense Medications in Compliance with California Law***	
	1.	Enter prescription information into patient profile
	2.	Document preparation of medication in various dosage forms
	3.	Prepare label(s) for prescription containers
	4.	Select auxiliary label(s) for container(s)
	5.	Prior to dispensing, perform the final check of the medication (e.g., correct drug, dose, route, directions)

California State Board of Pharmacy
California Pharmacist Jurisprudence Exam
Detailed Content Outline

2. Monitor, Communicate and Manage Patient Outcomes (31 Percent)

A. *Improve Patient Understanding, and Counsel Patient/Patient's Representative in Compliance with California Law*

1. Assess the patient's knowledge of the disease and treatment
2. Determine the need for a referral
3. Counsel patient/patient's representative regarding prescription medication therapy
4. Counsel patient/patient's representative regarding herbal/alternative therapies
5. Verify the patient's/patient representative's understanding of the information presented

B. *Monitor, Communicate, and Manage Patient Outcomes*

1. Communicate results of monitoring to patient/patient's representative, prescriber and/or other health care professionals
2. Adjust patient's drug therapy according to written protocols developed with prescriber(s)

3. Manage Operations in Accordance with California Law (40 Percent)

A. *Obtain and Document Pharmaceuticals, Devices and Supplies*

1. Maintain a borrow/loan system in compliance with legal requirements
2. Maintain a record-keeping system of items purchased/received/returned in compliance with legal requirements and professional standards

B. *Perform Quality Assurance/Improvement to Enhance Patient Safety and Meet Local Requirements*

1. Measure, assess and improve the accuracy of medication dispensing by pharmacy staff
2. Measure, assess and improve patient compliance/adherence with medication regimens
3. Measure, assess and improve the disease-management outcomes of patient populations

C. *Manage Operations, Human Resources and Information Systems*

1. Monitor the practice site and/or service area for compliance with federal, state and local laws, regulations and professional standards
2. Develop and implement policies and procedures for pharmacy technicians
3. Supervise the work of pharmacists, pharmacy technicians and/or other pharmacy staff
4. Ensure the availability of patient-related information (e.g., patient profiles, medication administration records)

D. *Establish and Manage Medication Use Systems in Accordance with Patient Safety Guidelines and California Law*

1. Apply therapeutic interchange (e.g., formulary substitution) guidelines
2. Establish and maintain a system by which adverse drug reactions are documented, analyzed, evaluated and reported
3. Establish and maintain a system for medication error reporting including root cause analysis

TOTAL: 90 QUESTIONS, INCLUDING 15 NONSCORED, PRETEST ITEMS

SAMPLE CPJE QUESTIONS

Overview

Provided below are samples of test questions. Each multiple-choice question on the examination has four possible answers. Only one answer is correct. These examples are provided to familiarize you with the structure of some of the questions.

Each question is worth one point, and there is no penalty for guessing.

The board encourages you to review the Content Outline for the CPJE, which is provided on Pages 8 and 9. The content outline describes the content areas and number of questions that will be used for each examination. You may find it helpful to prepare for the examination by using the content outline.

Questions:

1. A patient arrives with prescriptions for Soma® and Vicodin® and presents them to the intern pharmacist. He notices the prescriptions are written by a nurse practitioner with a furnishing number. The pharmacist should

   A. fill both prescriptions using the nurse practitioner's and supervising physician's names.

   B. refuse to fill both prescriptions.

   C. refuse to fill the Vicodin®, but fill the Soma®.

   D. fill the prescriptions using the supervising physician's name.

2. A patient has just been counseled on the appropriate use of his new prescription for bumetanide. Which of the following statements would verify that the patient has a good understanding of the possible side effects of the drug?

   A. "This medication can cause coughing."

   B. "This medication can cause muscle cramps."

   C. "I should report headaches to my doctor."

   D. "I should take this medication with food to avoid nausea."

3. A pharmacist has a protocol with a physician to manage the drug therapy of a 37-year-old patient with schizophrenia. The patient has been treated with clozapine for the past 4 months. The dose is 500 mg daily. The patient has the following past CBC results:

	WBC	Neutrophils
June 30	10.1	7.3
June 22	10.7	7.4
June 16	6.5	3.5
June 9	6.3	3.4
June 2	6.7	3.8

   On July 7, the patient's WBC is 7.2 and neutrophils are 4.3. The MOST APPROPRIATE decision regarding the weekly clozapine prescription for 500 mg daily is to

   A. fill as written.

   B. discontinue therapy.

   C. hold therapy for 1 week and resume at 400 mg daily.

   D. repeat CBC and fill if WBC is greater than 8.

4. A pharmacy prepares sterile parenteral products. Concerning good practice, which professional standards must be followed?

   A. California State Pharmacy Laws and Regulations

   B. Title 22

   C. JCAHO guidelines

   D. ISMP guidelines

5. A licensed paramedic from a city fire department asks a hospital pharmacy to furnish morphine sulfate pre-filled syringes that can be kept in the paramedic drug supply for use in emergency situations. Which of the following actions should the pharmacist take?

   A. Request that a physician from the city's health department provide a completed DEA Form 222 to the pharmacy.

   B. Advise the paramedic that Schedule II medications cannot be furnished without a valid triplicate prescription.

   C. Provide no more than 3 pre-filled syringes after recording the paramedic's name, license number, and department badge number.

   D. Inform the paramedic that a written request specifying the name and quantity of the medication must be submitted from the paramedic's fire department.

6. A physician administers fentanyl to patients during procedures performed in his office clinic. The physician wishes to order fentanyl from a pharmacy. The pharmacist should advise the physician to

   A. complete a DEA Form 222.

   B. complete a purchase order.

   C. write a regular prescription indicating "for office use."

   D. write a triplicate prescription indicating "for office use."

7. A patient comes into the pharmacy with a prescription for erythromycin. During consultation, the patient mentions that her new job in construction has made her allergies unbearable. The patient asks the pharmacist to call her physician for a new prescription for this condition. The physician asks for the pharmacist's recommendation. Which of the following antihistamines should be suggested for this patient?

   A. loratadine
   B. clemastine
   C. cetirizine
   D. diphenhydramine

8. A pharmacy clerk is typing a prescription for zolpidem. The pharmacy clerk pulls the medication from the stock and hands it to the pharmacy technician to fill. The technician fills the prescription and hands it to the pharmacist for the final verification. Which of the following actions should the pharmacist take?

   1. Confirm with the technician that the prescription was filled correctly, then sign the prescription, and dispense the medication.
   2. Do not dispense the medication since a pharmacy clerk cannot type new prescriptions.
   3. Do not dispense the medication since a pharmacy clerk cannot pull the medication from the stock.
   4. Do not dispense the medication since the pharmacy technician cannot fill controlled substances.

   A. 1 only
   B. 2 and 3 only
   C. 2 and 4 only
   D. 3 and 4 only

9. A pharmacist is checking the accuracy of medications that were to be repackaged into unit dose form by a pharmacy technician. The medication that was to be repackaged is Monopril®. Which of the following medications should have been used?

   A. quinapril
   B. moexipril
   C. fosinopril
   D. benazepril

10. A technician calls the pharmacist over to the computer to view a serious drug interaction noted by the software. What initial step should be taken in the further processing of the prescription order?

    A. Call the physician and suggest using a different drug.
    B. Override the interaction screen and fill the prescription.
    C. Review the profile and verify that the patient is still taking the first drug.
    D. Dispense the medication and counsel the patient on signs and symptoms of the drug interaction.

11. A pharmacist is computing the average adverse drug reaction (ADR) occurrence rate per patient days at the hospital for a quarterly report to the Pharmacy and Therapeutics Committee. The data that the pharmacist will use is listed below:

Month	ADRs Reported	Patient Days
January	289	3204
February	341	4023
March	256	2143

    Which of the following represents the average ADR occurrence rate for this quarter?

    A. 8.9%
    B. 9.5%
    C. 9.8%
    D. 10.1%

ANSWERS

1. A	7. A
2. B	8. D
3. A	9. C
4. A	10. C
5. D	11. C
6. A	

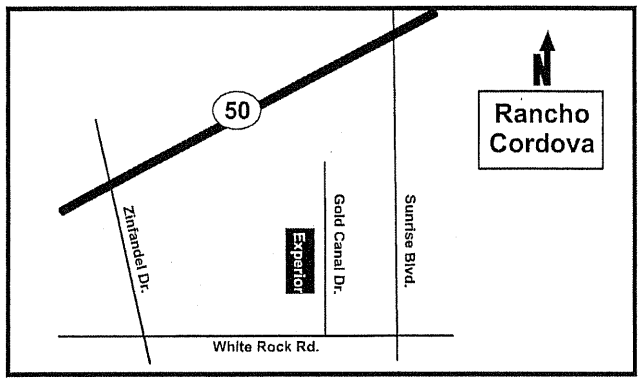
CALIFORNIA TESTING CENTERS

If you are unfamiliar with the area, please contact the testing center during testing hours for directions. Please direct registration, scheduling and any other questions to Experior at 800.894.9962

MAPS ARE NOT DRAWN TO SCALE.

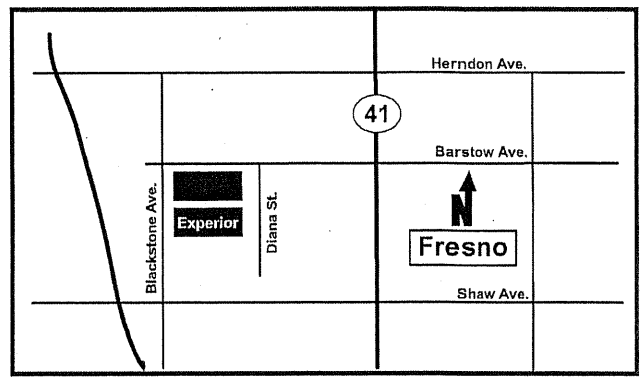
Rancho Cordova Center
3110 Gold Canal Drive, Suite E
Rancho Cordova, CA 95670
Phone: 916.851.8340

From Hwy 50, take either the Sunrise Blvd. or Zinfandel Dr. exit and head south. Turn on White Rock Rd. and turn again onto Gold Canal Dr. The Experior testing center is on your left. Turn into the first driveway on your left to park in front of the building. Additional parking is available around the building.



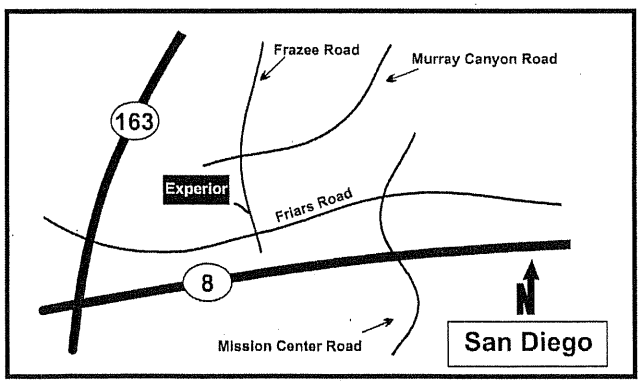
Fresno Center
125 E. Barstow Avenue, Suite 136
Fresno, CA 93710
Phone: 559.226.3334

From Hwy 41, exit west on Shaw; turn right (north) on Blackstone. From northbound I-99, exit east on Shaw; turn left (north) on Blackstone. Turn right (east) on Barstow. At 125 E. Barstow, turn right on Diana, and then right into the parking area. The Experior testing center is located in the second building from Barstow. Parking is available around the building.



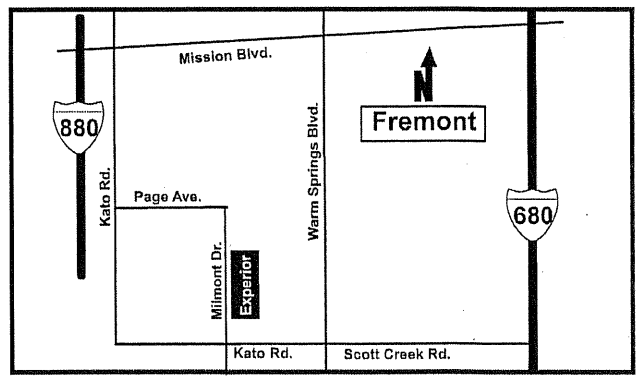
San Diego Center
1450 Frazee Road, Suite 410
San Diego, CA 92108
Phone: 619.574.1840

From Highway 163, take the Friars Road exit east to Frazee Road. Turn left (north) on Frazee Road. The Experior testing center is in the building on your left. Parking is available all around the building.



Fremont Center
48860 Milmont Drive, Suite 103C
Fremont, CA 94538
Phone: 510.687.0821

From I-880, take the Mission Blvd exit and head east; turn right (south) on Warm Springs Blvd, right again on Kato Rd and right again on Milmont Dr. From I-680, take the Scott Creek Rd exit and head west; Scott Creek Rd becomes Kato Rd; turn right on Milmont Dr. The Experior testing center is on your right. Parking is available around the building.

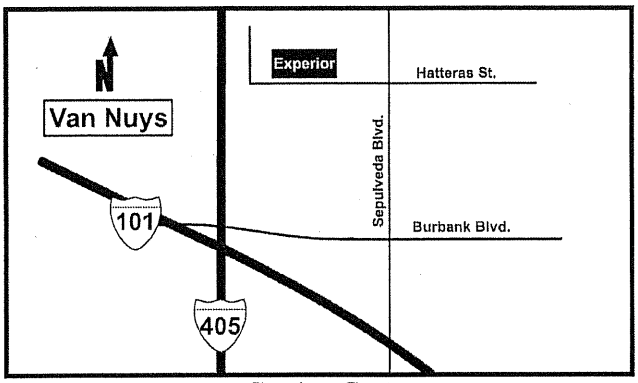


CALIFORNIA TESTING CENTERS (cont.)

Note: Maps are not drawn to scale.

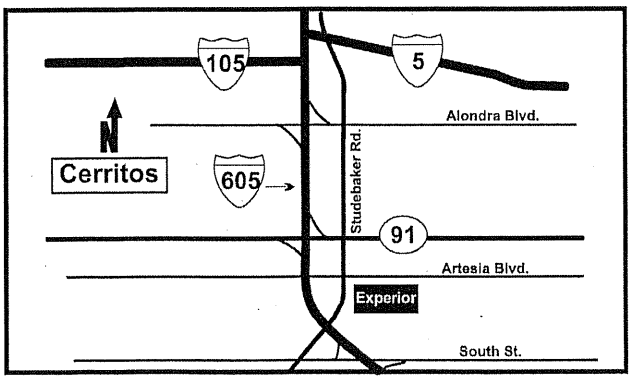
Van Nuys Center
John Laing Holmes Building
5805 Sepulveda Blvd., Suite 601
Van Nuys, CA 91411
Phone: 818.781.9981

From I-405, take the Burbank Blvd exit and head east; turn left (north) on Sepulveda Blvd. The Experior testing center is located at the intersection of Sepulveda and Hatteras. Paid parking is available in the lot; free parking may be available on the street.



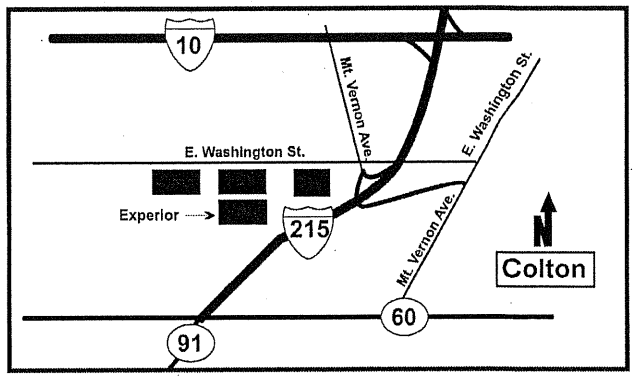
Cerritos Center
Caremore Building
18000 Studebaker Road, Suite 680
Cerritos, CA 90703
Phone: 562.860.1748

From I-605 south, take the Alondra Blvd exit, turn left (east) on Alondra Blvd and right (south) on Studebaker. From I-605 North, take the South Street exit; turn left (west) on South St. and right on Studebaker. Parking is available around the building.



Colton Center
Rancho Las Palomas
1060 E. Washington Street, Suite 110
Colton, CA 92324
Phone: 909.783.2255

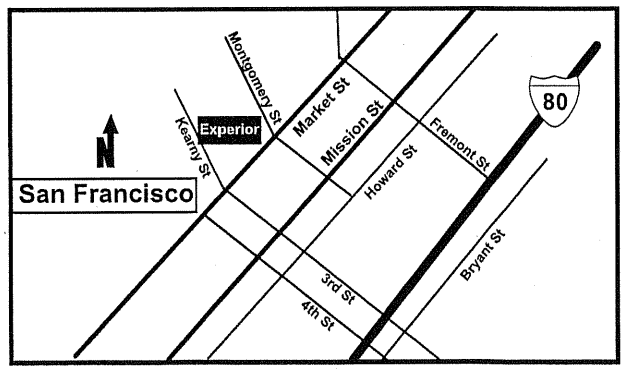
From I-215, take the Mt. Vernon Ave. exit; head west on E. Washington. The Experior testing center will be on your left, in the 2-story Rancho Las Palomas building behind Del Taco. Parking is available around the building.



San Francisco Area Center
222 Kearny Street, Suite 603
San Francisco, CA 94108
Phone: 415.834.1357

From I-80 heading south, take the Fremont Street exit and turn left. At the first intersection, turn left onto Howard Street. Turn right onto 3rd Street, which becomes Kearny Street. Experior is on the right-hand side of the road. **From I-80** heading north, take the 4th Street exit toward Embarcadero. Turn a slight left onto Bryant Street, then left onto 3rd Street. 3rd Street becomes Kearny Street. Experior is on the right-hand side of the road. Paid parking is available nearby. Please be prepared to pay for your parking

The nearest BART location is at the intersection of Montgomery Street ant Market Street. The building is also accessible by MUNI.



EXPERIOR
CALIFORNIA PHARMACY JURISPRUDENCE EXAMINATION REGISTRATION

for exams on or after March 1, 2004

Last Name	First Name	Middle Initial	Social Security Number ___ ___ ___-___ ___-___ ___ ___ ___
Residence Address (Street or P.O. Box)			Daytime Phone No. (including area code) ( )
City	State	ZIP Code	
Fax No (including area code) ( )	Evening Phone No (including area code) ( )		

Exam Title	Exam Fee	Total Fee Enclosed
California Pharmacy Jurisprudence Examination (CPJE)	$40.00	$

Fee may be paid by cashier's check, business check, money order, MasterCard or Visa. Make checks payable to Experior. Please put your Social Security number on the check. **PERSONAL CHECKS AND/OR CASH ARE NOT ACCEPTED. ADMINISTRATION FEES ARE NOT REFUNDABLE.** Testing fees are determined by the state of California and are subject to contractual change without notice. To pay by credit card, please complete the information below. To express register and schedule, visit our Web site at **www.experioronline.com** or call 800.869.6603. To register by mail, send this completed form with the appropriate fee to:

Experior Assessments
ATTN: Exam Registration
1260 Energy Lane
St. Paul, MN 55108

Card Type (Circle) MC Visa	Card Number	Expiration Date
Name of Cardholder (Print)	Signature of Cardholder	

CALIFORNIA STATE BOARD OF PHARMACY
400 R STREET, SUITE 4070
SACRAMENTO, CA 95814
TELEPHONE: 916.445.5014
www.pharmacy.ca.gov

STATE OF CALIFORNIA

NOTICE OF ELIGIBILITY

(Rev. 03/04)

You are eligible to participate in the California Pharmacy Jurisprudence Examination (CPJE). Your address label below contains important date information. In the upper left corner of the address label (above your name) is the date your application for examination was approved; following that is the date by which you must take your examination. You must take your examination by the date specified on the label, or you will need to reapply (see *Expiration of Examination Eligibility* on Page 3 of this handbook).

This handbook is designed to provide you with information regarding examination procedures and content areas. To schedule your examination, please refer to the instructions in this handbook. **You are responsible for calling the toll-free number listed under the *Scheduling the CPJE* portion of this handbook on Page 2 to schedule your examination date, time and location.** Schedule your examination early to get your preferred test center location and date, preferably within 90 calendar days of your eligibility date.

FIRST CLASS MAIL

ATTACHMENT I

State of California Department of Consumer Affairs

Memorandum

To: Licensing Committee Date: February 20, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Pharmacist Loan Repayment Program

Assembly Bill 2935 (Chapter 1138, Statutes of 2002) established the California Pharmacist Scholarship and Loan Repayment Program in the Office of Statewide Health Planning and Development (OSHPD). The bill established a mechanism for pharmacists and pharmacies to contribute $25 to a fund that would provide scholarships or loan forgiveness to pharmacists and pharmacy students who committed to serve in medically underserved communities. A copy of the legislation is attached for your reference (Attachment A).

The statute specifies that the program will only be implemented to the extent funding is made available. It permits both the contributions by renewing pharmacists and pharmacies and any other source of funding that can be identified and appropriated by the Legislature.

The bill also specifies that the program shall be administered using the criteria employed by the National Health Service Corps scholarship and loan repayment programs (excerpts from those program bulletins are attached for your reference). As a general matter, the programs provide funding to students and graduates who commit to provide health services in medically underserved communities for a two-year period. Funding is capped at $25,000 per year based on either the actual educational expenses or the total amount of qualified educational loans outstanding for the candidate.

Candidates are selected generally based on financial need and having characteristics that indicate a tendency to remain in the underserved community after their commitment has been completed.

Assembly Bill No. 2935

CHAPTER 1138

An act to add Section 4409 to the Business and Professions Code, and to add Article 2 (commencing with Section 128198) to Chapter 3 of Part 3 of Division 107 of the Health and Safety Code, relating to health professions.

[Approved by Governor September 30, 2002. Filed with Secretary of State September 30, 2002.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2935, Strom-Martin. Health professions: education: pharmacists: scholarship and loan repayment program.

Existing law provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. Existing law authorizes the imposition of a biennial license renewal fee upon pharmacists and an annual license renewal fee upon pharmacies.

This bill would authorize a pharmacist and pharmacy to make a $25 contribution at the time of renewing a license, the proceeds to be deposited in the California Pharmacist Scholarship and Loan Repayment Program Fund described below.

Existing law requires the Office of Statewide Health Planning and Development to perform various functions and duties with respect to health policy and planning and health professions development, including administering the federal National Health Service Corps Scholarship Program and the federal National Health Service Corps Loan Repayment Program. Under the existing programs, federal funds are provided to states for the purpose of providing scholarships to health professions students or repaying qualifying educational loans of specified health care professionals who commit to serve a specified time period as a provider of health services, at practice sites in designated health professional shortage areas. Under the existing programs, the practice site is also responsible for repaying a portion of the health care professional's outstanding loan amount.

Existing law establishes the Health Manpower Policy Commission and prescribes the powers and duties of the commission, which include identifying specific areas of the state where unmet priority needs for primary care family physicians exist.

This bill would establish in the office the California Pharmacist Scholarship and Loan Repayment Program to provide scholarships to pay for the educational expenses of pharmacy students and to repay

qualifying educational loans of pharmacists who agree to serve in areas of the state where unmet priority needs for primary care family physicians exist as determined by the Health Manpower Policy Commission.

The bill would require the office to administer the California Pharmacist Scholarship and Loan Repayment Program utilizing the same general guidelines applicable to the federal National Health Service Corps Scholarship Program and the federal National Health Service Corps Loan Repayment Program, with the exception that no matching funds shall be required from any entity in the practice site area.

The bill would establish the California Pharmacist Scholarship and Loan Repayment Program Fund in the State Treasury, and would require that the moneys in the fund be available for expenditure, upon appropriation by the Legislature, for purposes of implementing the program. The bill would provide that the program shall be implemented only to the extent that sufficient moneys are available in the fund.

The people of the State of California do enact as follows:

SECTION 1. Section 4409 is added to the Business and Professions Code, to read:

4409. At the time a pharmacy license is renewed pursuant to subdivision (a) of Section 4110 or a pharmacist license is renewed pursuant to Section 4401, the pharmacy or pharmacist may make a twenty-five dollar ($25) contribution, to be submitted to the board, for the sole purpose of funding the California Pharmacist Scholarship and Loan Repayment Program established pursuant to Article 5 (commencing with Section 128050) of Chapter 2 of Part 3 of Division 107 of the Health and Safety Code. The contribution submitted pursuant to this section shall be paid into the State Treasury and credited to the California Pharmacist Scholarship and Loan Repayment Program Fund established pursuant to Section 128051 of the Health and Safety Code.

SEC. 2. Article 2 (commencing with Section 128198) is added to Chapter 3 of Part 3 of Division 107 of the Health and Safety Code, to read:

Article 2. California Pharmacist Scholarship and Loan Repayment Program

128198. (a) (1) There is hereby established in the Office of Statewide Health Planning and Development the California Pharmacist Scholarship and Loan Repayment Program.

(2) The program shall provide scholarships to pay for the educational expenses of pharmacy school students and repay qualifying educational loans of pharmacists who agree to participate in designated medically underserved areas as provided in this section.

(b) The Office of Statewide Health Planning and Development shall administer the California Pharmacist Scholarship and Loan Repayment Program utilizing the same general guidelines applicable to the federal National Health Service Corps Scholarship Program established pursuant to Section 254*l* of Title 42 of the United States Code and the National Health Service Corps Loan Repayment Program established pursuant to Section 254*l*-1 of Title 42 of the United States Code, except as follows:

(1) A pharmacist or pharmacy school student shall be eligible to participate in the program if he or she agrees to provide pharmacy services in a practice site located in areas of the state where unmet priority needs for primary care family physicians exist as determined by the Health Manpower Policy Commission.

(2) No matching funds shall be required from any entity in the practice site area.

(c) This section shall be implemented only to the extent that sufficient moneys are available in the California Pharmacist Scholarship and Loan Repayment Program Fund to administer the program.

128198.5. The California Pharmacist Scholarship and Loan Repayment Program Fund is hereby established in the State Treasury. Revenues from the contributions made pursuant to Section 4409 of the Business and Professions Code, as well as any other private or public funds made available for purposes of the California Pharmacist Scholarship and Loan Repayment Program, shall be deposited into the fund. Upon appropriation by the Legislature, moneys in the fund shall be available for expenditure by the Office of Statewide Health Planning and Development for purposes of implementing the California Pharmacist Scholarship and Loan Repayment Program pursuant to this article. The Office of Statewide Health Planning and Development shall be under no obligation to administer a program under this article until sufficient moneys have been accumulated in the fund and appropriated to the office by the Legislature.

O

U.S. Department of Health and Human Services

HRSA

Health Resources and Services Administration

Bureau of Health Professions

NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM

FISCAL YEAR 2004 APPLICANT INFORMATION BULLETIN

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Bureau of Health Professions
Division of National Health Service Corps
Application and Award Branch
5600 Fishers Lane, Room 8 A-55, Rockville, MD 20857

For inquires specific to the National Health Service Corps (NHSC) Loan Repayment Program application process call or write:

Division of National Health Service Corps
NHSC Loan Repayment Program
c/o I.Q. Solutions
11300 Rockville Pike, Suite 801
Rockville, Maryland 20852
1-800-638-0824
Email Address: NHSC@iqsolutions.com

A. INTRODUCTION

1. Purpose of the National Health Service Corps (NHSC) Loan Repayment Program (LRP)

The purpose of the NHSC LRP is to ensure an adequate supply of health professionals to provide primary health services (through a culturally competent, interdisciplinary team of clinicians) to populations located in selected health professional shortage areas (HPSAs) identified by the Secretary of the Department of Health and Human Services. HPSAs can be found in rural and urban communities across the Nation. The NHSC LRP recruits fully trained health professionals who agree to provide primary health services in NHSC community sites. In return, the NHSC LRP assists clinicians in their repayment of qualifying educational loans that are still owed. The NHSC is seeking clinicians that demonstrate the characteristics for and interest in serving the Nation's medically underserved populations and remaining in HPSAs beyond their service commitment. It is important to remember that service to medically underserved populations is the primary purpose of the NHSC LRP and not the repayment of educational loans.

2. Important Items for Applicants to Consider:

- **The NHSC LRP is a highly competitive program with limited funding. An NHSC LRP contract award is contingent upon availability of funds.**

- **The Checklist at Section W of this Bulletin sets out the application documents that must be submitted for an application to be complete. These documents must be submitted by no later than March 26, 2004 (postmark date). However, if certain documents (see Section M.2. of this Bulletin) are not available prior to March 26, 2004, those documents must be submitted by no later than July 23, 2004 (postmark date). An application will not be considered complete until all required items, as set forth in the Checklist, are submitted. Applications that are incomplete when initially submitted cannot be supplemented (except for the items set forth in Section M.2. of this Bulletin).**

- **Reference materials needed to complete this application are available on the NHSC Web site. The NHSC Web site can be found at http://nhsc.bhpr.hrsa.gov.**

- Employment at a community site posted on the NHSC Opportunities List does not guarantee an NHSC LRP contract award.

- No service credit will be given for employment at a community site before the effective date of an NHSC LRP contract award. The effective date of a contract award is the date the contract is countersigned by the Director of the Division of National Health Service Corps. Service credit will commence upon the effective date of the contract or the date service begins, whichever is later.

- Only the Division of National Health Service Corps can make an NHSC LRP contract award. An NHSC LRP contract award cannot be guaranteed by a community site, a Health Resources and Services Administration (HRSA) Field Office, a Primary Care Office, a Primary Care Association, or any person or entity other than the Director of the Division of National Health Service Corps.

- Funds provided under the NHSC LRP for loan repayment must be used to repay qualifying educational loans.

- NHSC LRP participants cannot be guaranteed a contract amendment (additional loan repayment funds) for continued participation in the program beyond the initial 2-year contract period.

3. Statutory Authority and Program Administration

The NHSC LRP is authorized by Public Law 100-177, enacted December 1, 1987 [Section 338B of the Public Health Service (PHS) Act, 42 United States Code, Section 254l-1], as amended on November 16, 1990, by Public Law 101-597 and on October 26, 2002, by Public Law 107-251. It is administered by the Division of National Health Service Corps, Bureau of Health Professions, Health Resources and Services Administration, an agency of the U.S. Department of Health and Human Services.

B. DEFINITIONS

Commercial Loans - Commercial loans are defined as loans made by banks, credit unions, savings and loan associations, insurance companies, schools, and other financial or credit institutions which are subject to examination and supervision in their capacity as lenders by an agency of the United States or of the State in which the lender has its principal place of business.

Division of National Health Service Corps (DNHSC) - An operating division of the Bureau of Health Professions, Health Resources and Services Administration.

Fiscal Year (FY) - The Federal FY is defined as October 1 through September 30.

Government Loans - Government loans are loans, which are made by Federal, State, county or city agencies, which are authorized by law to make such loans.

Health Professional Shortage Area (HPSA) – A HPSA is a geographic area, population group, public or nonprofit private medical facility or other facility determined by the Secretary of Department of Health and Human Services to have a shortage of primary health care professionals. HPSAs may be identified on the basis of agency or individual requests for designation. Information considered when designating a primary care HPSA include health provider to population ratios, rates of poverty, and access to available primary health services. These HPSAs are designated by the Bureau of Health Professions pursuant to Section 332 of the PHS Act (Title 42, U.S. Code, Section 254e) and implementing regulations (Title 42, Code of Federal Regulations, Part 5).

Health Resources and Services Administration (HRSA) - An operating agency of the U.S. Department of Health and Human Services.

Holder - The commercial or Government institution that currently holds the promissory note for the qualifying educational loan.

Lender - The commercial or Government institution that initially made the qualifying loan.

National Health Service Corps (NHSC) - "The Emergency Health Personnel Act of 1970," Public Law 91-623, established the NHSC on December 31, 1970. The NHSC Program, within the Department of Health and Human Services, was created to eliminate the health professional shortages in HPSAs through the assignment of trained health professionals to provide primary health services in HPSAs. The NHSC seeks to improve the health of underserved Americans by bringing together communities in need and quality primary health care professionals.

National Health Service Corps (NHSC) Loan Repayment Program (LRP) - The NHSC LRP is authorized by Section 338B of the PHS Act. Under the NHSC LRP, clinicians provide primary health services in HPSAs in exchange for funds for the repayment of their qualifying educational loans, plus tax assistance. The NHSC LRP identifies fully trained and licensed primary health care clinicians dedicated to meeting the health care needs of medically underserved communities.

Qualifying Educational Loans - Qualifying educational loans are Government and commercial loans for actual costs paid for tuition and reasonable educational and living expenses related to the undergraduate or graduate education of the participant leading to a degree in the health profession in which the participant will satisfy his or her NHSC LRP service commitment. Such loans must have documentation that is contemporaneous with the education received. Participants will receive funds for repayment of qualifying educational loans that are still owed. If the applicant has refinanced educational loans with any other debt, the refinanced loan will not be eligible.

Reasonable Educational Expenses - Reasonable educational expenses are the costs of education, exclusive of tuition, such as fees, books, supplies, clinical travel, educational equipment and materials, which do not exceed the school's estimated standard student budget for educational expenses for the participant's degree program and for the year(s) of that participant's enrollment.

Reasonable Living Expenses - Reasonable living expenses are the costs of room and board, transportation and commuting costs, and other costs which do not exceed the school's estimated standard student budget for living expenses at that school for the participant's degree program and for the year(s) of that participant's enrollment.

State - As used in this *Bulletin,* State includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Marianas, the U.S. Virgin Islands, Territory of American Samoa, Territory of Guam, Republic of Palau, Republic of the Marshall Islands, and Federated States of Micronesia.

2. Funding Preferences

Among applicants who have submitted timely and complete applications and have been determined by the NHSC to meet the eligibility criteria, the following funding preferences apply:

a. Information provided in an applicant's Biographical Statement and an applicant's disadvantaged background status will be considered. The NHSC is seeking individuals who demonstrate characteristics that they are likely to remain in a HPSA.

b. A funding preference will be given to applicants serving in HPSAs of greatest need (based on the HPSA scores). The HPSA score on the date the application is submitted (i.e., date received by the NHSC LRP) will be the HPSA score used for the FY 2004 award process. Awards will be made on an ongoing basis to applicants who propose to serve an NHSC community with a HPSA score of 14 or above. Applicants who propose to serve an NHSC community with a HPSA score of less than 14 will not be funded until after March 26, 2004, and will be funded after that date, by decreasing HPSA score, only to the extent funding remains available.

c. In order to distribute the number of NHSC LRP clinicians across a larger array of NHSC community sites, a maximum of two 2-year contract awards will be allowed per discipline category (i.e., primary health care, dental health care, mental health care) for each community site. Within each discipline category, the following additional limits apply:

- ***Primary health care:*** no more than one MD/DO and one NP/PA/NM
- ***Dental health care:*** no more than one DDS/DMD and one DH
- ***Mental health care:*** no more than one MD/DO and one CP/SW/MFT/PNS/LPC

d. If funding remains available after applying the above criteria, the NHSC LRP may allow up to four 2-year contract awards per discipline category for each community site. Eligible applicants would be funded by decreasing HPSA score.

e. If the vacancies at the community sites exceed the numbers allowed per site, it will be the community sites' responsibility to determine which of those vacancies will have the potential for NHSC loan repayment.

f. Community demand for each discipline category may be considered, in the event funding is insufficient to fund all eligible applicants at sites, which have the same HPSA score.

g. The NHSC LRP will select awardees and alternates consistent with the above funding preferences. Alternates will be funded to the extent awardees decline their awards. All FY 2004 NHSC LRP 2-year contracts will be awarded no later than September 30, 2004.

D. SERVICE REQUIREMENTS

1. 2-Year Service Requirement

Every NHSC LRP participant must sign a contract agreeing to provide 2 years of full-time clinical service in a community site/vacancy on the NHSC Opportunities List. See Sections G and H of this *Bulletin*.

2. Contract Amendment Awards

Participants in good standing may have the opportunity to request amendments of their NHSC LRP contracts to continue their service (and loan repayments), to the extent those participants continue to have unpaid qualifying educational loans. Amendments to NHSC LRP contracts will be made at the Government's discretion and are subject to the availability of funds appropriated by the United States Congress for the NHSC LRP. Thus, there is no guarantee that a 2-year service commitment (contract) will be amended beyond the initial 2 years. Applicants for contract amendments must continue to meet the eligibility criteria and must be in full compliance with their existing NHSC LRP service obligation.

The amendment service period must begin immediately following the completion of the initial service commitment (i.e., no break in service between the contracts is allowed). The contract amendment will not become effective until the participant has fully completed the initial NHSC LRLP service commitment. If a participant breaches the terms and conditions of the initial NHSC LRP contract award, including the requirement that loan repayments received must be applied to reduce the participant's qualifying educational loans during the period of obligated service, he or she will not receive a contract amendment.

E. BENEFITS

1. Loan Repayments

The NHSC LRP will provide funds to program participants to repay their outstanding qualifying educational loans (See Section F).

a. For the first 2 years of service, the NHSC LRP will pay up to $25,000 for each year of service, based on the participant's outstanding balance of qualifying educational loans. If the total amount of the participant's qualifying educational loans is less than $50,000, the NHSC LRP will pay one-half of the total qualifying educational loans annually.

b. **All loan repayments paid to the participant must be used by the participant to repay the approved qualifying educational loans.**

2. Tax Assistance

In addition to the loan repayments, participants are entitled to tax assistance payments equal to 39 percent of the total amount of loan repayments received during a tax year. **The loan repayments and the tax assistance payments are taxable income and will be reported to the Internal Revenue Service (IRS).** The IRS has determined that employment tax also applies to NHSC LRP awards. The tax assistance payment will be paid to the IRS directly on the participant's behalf.

3. Methods of Disbursing Payments

To assist NHSC LRP participants in reducing their educational debts in a shorter period of time, the NHSC LRP will disburse payments to participants on an advanced basis (either quarterly, biannually, annual or lump sum). **Switching between methods of payment may be allowed only at the beginning of a new NHSC LRP service year. Please note, however, that all requests to switch between methods of payment must be submitted in writing at least 3 months prior to the beginning of that service year.**

After receipt of the first payment, any subsequent payments will be contingent upon the NHSC's timely receipt of a 6-month verification form confirming that participant's compliance with the NHSC full-time clinical service requirement. See Section H of this *Bulletin*.

Applicants are encouraged to seek financial counseling before selecting one of the advanced payment methods. Because of the timing of the payment methods, the participant's annual taxable income may increase significantly and he or she should seek advice regarding the tax ramifications of this action. In addition, applicants should contact their lenders regarding prepayment options. Some lenders will accept the advanced payment, but expect the participant to continue to make monthly payments.

Note: Under the Treasury Offset Program, the Treasury Department is authorized to offset NHSC LRP payments for delinquent Federal and State debts, including delinquent child support payments.

4. **Salary**

The NHSC LRP participant will receive a salary and benefits from the employing community site. Employment compensation packages are negotiated between the professional and the community site. NHSC loan repayments must not be part of the salary negotiations between clinicians and community sites. The community site cannot guarantee an NHSC LRP contract award. NHSC LRP participants should carefully review their employment contracts to ensure these issues are addressed.

F. QUALIFYING EDUCATIONAL LOANS

1. Loans Qualifying for Repayment - NHSC LRP participants will receive monies to be applied to the principal, interest, and related expenses of **Government (Federal, State, or local) and commercial loans** obtained by the participant for:

a. school tuition and required fees;

b. other reasonable educational expenses (see Definitions, Section B of this *Bulletin*); and

c. reasonable living expenses (see Definitions, Section B of this *Bulletin*).

The fees and expenses listed above are limited to those incurred by the participant for undergraduate or graduate education leading to a degree in the health profession in which the participant will satisfy his or her NHSC LRP service commitment.

2. Loans <u>Not</u> Qualifying for Repayment - The following are examples of financial obligations that **do not** qualify for repayment by the NHSC LRP:

a. loans for which the associated documentation does not support that the loans were made for the purpose of undergraduate or graduate education leading to a degree in the applicant's NHSC LRP health profession in which he or she will be serving or that the loans were made contemporaneous with such education;

b. loans not obtained from a Government entity or commercial lending institution (see Definitions, Section B of this *Bulletin*). Most loans made by private foundations are not eligible for repayment.

c. loans, or that portion of loans, obtained for educational or living expenses which exceed the school's estimated standard student budget in the year the loan was made and the student is unable to substantiate, to the NHSC LRP's satisfaction, that the excess educational and/or living expenses were reasonable; and

d. loans that have been repaid in full.

3. Refinanced Loans

If eligible educational loans are refinanced, the original loan documentation must be submitted to establish the educational purpose and contemporaneous nature of such loans. The refinanced loan must be from a Government (Federal, State, or local) and commercial lender for the applicant's qualifying educational loans only. If an educational loan is refinanced with other debt, the refinanced loan is not eligible for loan repayment.

G. COMMUNITY SITE EMPLOYMENT

1. General Information

In exchange for NHSC LRP benefits, NHSC LRP participants must be engaged in the full-time clinical practice (see Section I.) of their professions at a community site on the NHSC Opportunities List. The NHSC Opportunities List includes specific primary health care employment opportunities in federally designated HPSAs that have been identified by the NHSC as significantly lacking certain health professionals. The NHSC community sites provide ambulatory primary health services to populations residing in HPSAs throughout the Nation.

The NHSC Opportunities List is prepared each year by the Division of National Health Service Corps. This List reflects approved NHSC vacancies. The NHSC Opportunities List for FY 2004 will be posted on the NHSC Web Site. The NHSC Opportunities List can be found at *http://www.nhsc.bhpr.hrsa.gov* under Opportunities. Only those vacancies on the NHSC Opportunities List no later than March 26, 2004, will be considered for FY 2004 NHSC LRP 2-year contract awards.

Community sites may have several vacancies per discipline category posted on the NHSC Opportunities List. Initially, no more than two vacancies per discipline category will be filled through the NHSC LRP. See Section C. 2.c. of this *Bulletin.* If funding remains available, the NHSC LRP may allow up to four 2-year contract awards per discipline category for each community site. If the vacancies at the community sites exceed the numbers allowed per site, it will be the community sites' responsibility to determine which of those vacancies will have the potential for NHSC loan repayment.

At the time the application is submitted, the applicant must, at a minimum, be in the final stages of negotiating an employment contract with an NHSC community site. The NHSC LRP community site information form (see Section O of this *Bulletin*), documents the applicant's employment negotiation status. **This form must be submitted with the application by March 26, 2004 (postmark date).**

During contract negotiations, the applicant and the NHSC community site should agree upon a start date. That start date must be **on or before September 30, 2004.**

An applicant's acceptance of an offer of employment to fill a vacancy on the NHSC Opportunities List does not guarantee that the applicant will subsequently receive an NHSC LRP contract award. See Section C of this *Bulletin* describing the eligibility requirements and funding preferences used by the NHSC LRP to determine which applicants will receive NHSC LRP contract awards.

Applicants become participants in the NHSC LRP (i.e., the contract becomes effective) on the date the Director of the Division of the National Health Service Corps countersigns the NHSC LRP contract. The applicant's signature alone on this contract does not constitute a contractual agreement.

When the employment start date precedes the effective date of the NHSC LRP contract, no NHSC LRP service credit will be approved for employment prior to the effective date of the contract and no loan repayments will be made for any professional practice performed before the effective date of the contract.

2. Serving Under a Private Practice Assignment (PPA) Agreement

Under the PPA, an individual serves at a public or private entity on the NHSC Opportunities List, is subject to the personnel system of the entity to which he or she is assigned and must receive an income at least equal to the income he or she would have received as a civilian employee of the U.S. Government. All Private Practice Assignees are required to accept assignment under the Medicare Program and to enter into appropriate agreements with the Medicaid and State Children's Health Insurance Programs. Entities employing Private Practice Assignees must have a schedule of discounts (including, as appropriate, waivers) of fees based on a patient's ability to pay.

3. Serving Under a Private Practice Option (PPO) Agreement

Under the PPO, an individual is self-employed or is a salaried employee of a public or private entity. Such service must be at a community site identified on the NHSC Opportunities List as a PPO site. The PPO Agreement requires, among other things, that a participant: accept Medicare assignment; enter into appropriate agreements under the Medicaid and State Children's Health Insurance Programs; provide services at no charge, or at a nominal charge, to those persons unable to pay for services; and submit reports and documents, as required, relating to the conduct of his or her practice.

H. FULL-TIME CLINICAL PRACTICE

Every participant is required to engage in the full-time clinical practice of the profession for which he or she was awarded an NHSC LRP contract. Full-time clinical practice is defined as a minimum of 40 hours per week. For physicians, the practice will include ambulatory care, as well as hospital care appropriate to meet the needs of patients and to assure continuity of care.

For all health professionals, except obstetrician/gynecologist (OB/GYN) physicians and certified nurse midwives, at least 32 of the minimum of 40 hours per week must be spent

providing clinical services. These services must be conducted during normally scheduled clinic hours in the ambulatory care setting office(s) specified in the PPA or PPO Agreement. The remaining hours must be spent providing inpatient care to patients of that clinic and/or in practice-related administrative activities.

For OB/GYN physicians and certified nurse midwives, at least 21 of the minimum 40 hours per week must be spent providing clinical services. These services must be conducted during normally scheduled clinic hours in the ambulatory care setting office(s) specified in the PPA or PPO Agreement. The remaining hours must be spent providing inpatient care to patients of that clinic and/or performing practice-related administrative activities, with administrative activities not to exceed 8 hours per week.

The 40 hours per week may be compressed into no less than 4 days per week, with no more than 12 hours of work to be performed in any 24-hour period. Time spent in "on-call" status will not count toward the 40-hour week. Hours worked over the required 40 hours per week will not be applied to any other workweek.

No more than 7 weeks (35 workdays) per year can be spent away from the practice for vacation, holidays, continuing professional education, illness, or any other reason. Absences greater than 7 weeks in an NHSC LRP service year will extend the service commitment end date.

Every NHSC LRP participant must complete and submit a verification form for each 6 months of service. The form, which is signed by the participant and an appropriate official at the NHSC community site, will verify the participant's compliance/noncompliance with the full-time clinical practice requirement during that 6-month period. The form will also record the participant's time spent away from the practice site during that 6-month period. Continued receipt of loan repayment benefits will be contingent on a participant's timely submission of the 6-month verification form. See Section E.3. of this *Bulletin.*

I. LEAVING THE COMMUNITY SITE (CHANGING JOBS)

The NHSC LRP contract does not specify a particular community site, only that a participant will serve in the HPSA to which he or she is assigned by the Secretary of the Department of Health and Human Services. The NHSC expects that a participant will serve his or her full commitment at the initial placement site. Transfer requests are discouraged in order to minimize the disruption of patient care, and they will generally not be considered before completion of the first full year of service. Participants who are terminated by their NHSC community sites for cause are not entitled to transfers and will be placed in default.

Should participants be unable, through no fault of their own, to complete their agreed upon obligations at their initial NHSC community sites, they will be expected to continue their service, without a break, at other NHSC community sites. The transfer site will be based on the needs of the NHSC. Final approval of all transfers rests with the Division of NHSC, and approvals will be to sites of equal or greater need than the original site. If a participant does not accept his or her transfer site, he or she may be placed in default of his or her NHSC LRP contract.

If there is no break in service between the initial site and the transfer site, the participant will continue to receive loan repayments. However, if a participant fails to resume service

U. S. Department of Health and Human Services

HRSA

Health Resources and Services Administration

BUREAU OF HEALTH PROFESSIONS

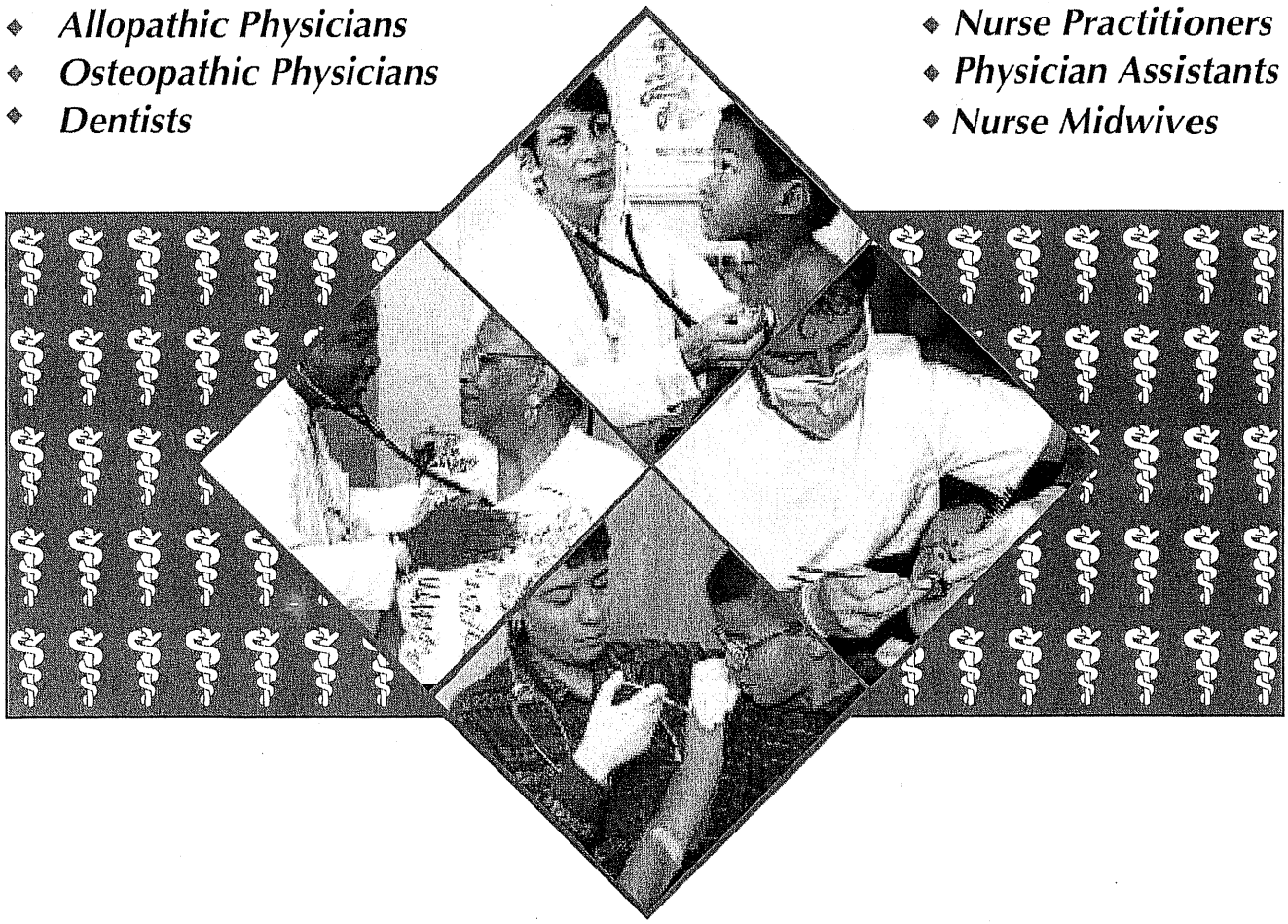
SCHOLARSHIP PROGRAM

Applicant Information Bulletin

2004•2005

For Students in Training to Become

- ***Allopathic Physicians***
- ***Osteopathic Physicians***
- ***Dentists***
- ***Nurse Practitioners***
- ***Physician Assistants***
- ***Nurse Midwives***



December 2003

BUREAU OF HEALTH PROFESSIONS

MISSION: The mission of the Bureau of Health Professions (BHPr) is to improve the health status of the population by providing national leadership in the development, distribution and retention of a diverse, culturally competent health workforce that provides the highest quality care for all.

INTRODUCTION

Program Purpose

The United States Congress has charged the National Health Service Corps (NHSC) with the responsibility for alleviating the geographic maldistribution of primary care physicians and other health practitioners in the United States.

The NHSC Scholarship Program is mandated by Congress to supply the NHSC with health care professionals trained in those disciplines and specialties most needed to deliver quality primary health care services in health professional shortage areas (HPSAs) throughout the United States as designated by the Secretary.

The NHSC Scholarship Program is not a general financial assistance program for students of health-related disciplines; rather, it provides the NHSC with the committed health professionals it needs to carry out its mission of providing primary health care to HPSA populations in areas of greatest need.

National Health Service Corps Scholarship Program Profile

The National Health Service Corps (NHSC) Scholarship Program is a competitive Federal program, which awards scholarships to students pursuing primary care health professions training.

The scholarship consists of payment for tuition, fees, other reasonable educational costs, and a monthly support stipend. In return, the students agree to provide 1 year of service in the HPSA of greatest need to which they are assigned for each school year or partial school year of scholarship support received, with a minimum 2-year service commitment, maximum 4-year commitment.

For the 2004-2005 academic year, scholarships will be available for students pursuing primary health care training leading to a degree in allopathic medicine, osteopathic medicine, or dentistry, and education leading to a degree as a family nurse practitioner, nurse-midwife or physician assistant.

*NHSC scholarship recipients **MUST** be **willing** and are **required** to fulfill their NHSC service commitment at HPSA locations selected by the NHSC, anywhere in the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Territory of Guam, the Commonwealth of the Northern Marianas, the U.S. Virgin Islands, the Territory of American Samoa, the Republic of Palau, the Republic of the Marshall Islands, or the Federated States of Micronesia.*

The scholarship recipient's service commitment will be fulfilled either as a non-Federal employee, as a commissioned officer of the Regular or Reserve Corps of the U.S. Public Health Service (PHS), or as a civilian employee of the U.S. Government. It should be noted that approximately 92% of scholars fulfill their commitments as non-Federal employees of public or private entities such as community and migrant health centers, health departments, and other non-Federal entities. Also note that the remaining 8% of scholars serve as Federal employees at HPSA sites in the Indian Health Service, the medical facilities of the Department of Justice's Federal Bureau of Prisons and the Immigration Health Service.

Students who are uncertain of their commitment to primary health care practice in HPSAs throughout the United States or who are unable to relocate based on the needs of the NHSC are advised not to participate in this program. Medical students (osteopathic and allopathic) who are unsure about their future specialty interests or who are unable to commit themselves to complete specialty training in one of the approvable primary care residencies specified in this *Bulletin* are advised not to apply for the NHSC scholarship.

Health Professional Shortage Areas (HPSAs)

A HPSA is a geographic area, a facility, or a population group, which has been determined by the Secretary of the Department of Health and Human Services to have a shortage of health professionals. HPSAs are identified on the basis of agency or individual requests for designation. Information considered when designating a primary care HPSA includes health practitioner-to-population ratios, rates of poverty, and access to available primary health services. **Service commitments to the NHSC may be satisfied ONLY in**

INTRODUCTION (Continued)

those HPSAs with the greatest need at the time of assignment, as determined by the Division of National Health Service Corps.

Program Administration

The Division of National Health Service Corps (DNHSC), Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA) administers the Scholarship Program. The DNHSC awards the scholarships, monitors scholars while in school and in deferment for advanced training, identifies appropriate service sites, assists scholars in securing employment at one of the eligible sites at the completion of their training, reviews and approves requests for transfers, and monitors scholars' service until they have completed their service commitment. The Legal and Compliance Branch, Office of Policy and Planning, assists scholars in staying in compliance and reviews requests for suspensions and waivers.

APPLICANT ELIGIBILITY

Applicants must meet the following requirements in order to be eligible for scholarship awards.

U.S. Citizenship

Scholarship applicants must be citizens or nationals of the United States to receive NHSC scholarship awards. Applicants who were born outside of the United States must submit documentation to verify U.S. citizenship (see Instructions for Completing Application, Section A, Item 6.).

Full-time Enrollment in Fully Accredited Schools and Programs (Note: Program must be fully accredited by April 2004).

To be considered for a scholarship award for the 2004-2005 academic year, applicants must be enrolled or accepted for enrollment as full-time students, and begin classes on or before January 2, 2005. **Please be advised that any non-required or unrelated courses will not count toward the schools required hours in determining full-time status.** The following is a listing of acceptable schools/programs:

(1) A school of allopathic medicine or osteopathic medicine, pursuing the M.D. or D.O. degree, fully accredited by the American Medical Association Liaison Committee on Medical Education or the American Osteopathic Association.

(2) A school of dentistry, pursuing the D.D.S. or D.M.D. degree, fully accredited by the Commission on Dental Accreditation of the American Dental Association.

(3) A school or program of family nurse practitioner (FNP) education pursuing a master's degree or post-master's certificate, fully accredited by the National League for Nursing Accrediting Commission or the Commission on Collegiate Nursing Education, and leading to national certification as a family nurse practitioner by either the American Nurses Credentialing Center or the American Academy of Nurse Practitioners.

(4) A school or program of nurse-midwifery (NM) education pursuing a master's degree or post-master's certificate, fully accredited by the American College of Nurse-Midwives (ACNM) and leading to national certification by the ACNM.

PLEASE NOTE: The NHSC Scholarship Program WILL NOT provide scholarship support for those students who are enrolled in nursing Bridge Programs (e.g., RN-MSN, BSN-MSN, Direct Entry or Entry-to-Practice Programs) or who are pursuing a doctoral degree in nursing.

Certified nurse midwives and certified family nurse practitioners MUST be able to obtain both a license and certification to practice in ANY State once they complete their training.

(5) A school or program of primary care physician assistant (PA) education where the applicant will 1) graduate from a full 4-year baccalaureate PA training program with a bachelor's or master's degree, or 2) graduate from a certificate, post-baccalaureate certificate, associate or master's degree PA training program of at least 12 months, and demonstrate a broad background knowledge of the medical environment, practices, and procedures, e.g., would be acquired by a) a bachelor's degree in a health care occupation such as nursing, medical technology, or physical therapy, or b) 3 years of responsible and progressive health care experience, e.g., a medical corpsman, nursing assistant or medical technician prior to enrolling in the PA training program.

Physician Assistant applicants pursuing an associate or master's degree or a certificate who do not have a bachelor's degree in nursing, medical technology or physical therapy must

APPLICANT ELIGIBILITY (Continued)

submit, by March 26, 2004, a resume outlining related health care education and work experience (including periods of employment and number of hours worked per week).

The PA training program must be accredited (provisional, initial or continuing) by the Accreditation Review Commission on Education for the Physician Assistant and affiliated schools must be accredited by a U.S. Department of Education nationally recognized regional or State institutional accrediting agency. The PA training program must lead to the national certification by the National Commission on Certification of Physician Assistants.

Please Note: Students who are in the "pre-professional" phase (e.g., pre-PA programs) or who are in PA programs specializing in areas other than primary care (e.g., PA programs with a surgical or emergency room focus) are not eligible for NHSC scholarship funding.

ALL STUDENTS – PLEASE NOTE: The NHSC Scholarship Program WILL NOT provide scholarship support for any joint programs that provide dual degrees in the above-listed disciplines (e.g., a joint program leading to a dual FNP/CNM degree).

Masters of Public Health

The NHSC Scholarship Program will not pay for a Masters of Public Health (MPH). If a student receives a one-year leave-of-absence from school to pursue an MPH, all scholarship support during that year will be discontinued. If a student decides to pursue an MPH in an integrated program, the NHSC Scholarship Program 1) will not pay for the MPH course work and 2) will only count the course work required for the scholarship-supported degree in determining whether the student is full-time (which may result in scholarship support being discontinued). See the "Discontinuation of Benefits" section of this *Bulletin*.

Schools and Programs Must be Located in the U.S.

The schools and educational programs for which scholarship support is requested must be in a State, the District of Columbia, or the Commonwealth of Puerto Rico. Students attending schools outside of these geographic areas are not eligible for NHSC scholarships, even though they may be citizens of the United States.

Eligibility for Federal Employment

Most NHSC Scholarship Program recipients should expect to serve their commitments as salaried non-Federal employees of public or private entities approved by the NHSC for the assignment of members of the NHSC. However, there may be vacancies which require Federal employment. In view of the potential for Federal employment, an applicant must be eligible to hold an appointment as a commissioned officer in the Regular or Reserve Corps of the PHS or be eligible for a Federal civil service appointment.

Submission of Authorization to Release Information Letter

To be eligible for an NHSC scholarship award, the applicant must complete, sign and return to the NHSC the Authorization to Release Information Letter enclosed in the back of this *Bulletin*. The NHSC Scholarship Program requires that all applicants submit the Authorization to Release Information Letter in order for the NHSC Scholarship Program to receive enrollment information from the applicant's school.

Submission of Signed Contract

To be eligible for an NHSC scholarship, the statute requires that an applicant sign and submit a contract with the application. The contract is located in the back of this *Bulletin*.

The contract is for the 2004-2005 school year with optional contracts for up to 3 subsequent school years. The 2004-2005 contract, if countersigned by the DNHSC, obligates the applicant to the minimum 2-year service commitment. Therefore, applicants are strongly encouraged to sign the 2004-2005 contract and an optional contract for the 2005-2006 school year, if the applicant will need additional support for all or part of the next school year (2005-2006). The contract ***must*** be signed through the student's date of graduation in order for the student to receive support through the date of graduation. **Before an applicant decides not to request scholarship support through his/her graduation date, the applicant should read the "Continuing Support After the 2004-2005 School Year" section of this *Bulletin*.**

Free of Federal Judgment Liens

Applicants who have a court judgment entered against them for a debt owed to the United States which creates a lien against their property are precluded from receiving Federal funds (including an NHSC Scholarship Program award), until the judgment lien has been paid in full or otherwise satisfied. A State court judgment relating to a Federal debt will also disqualify an applicant. The Application for Participation includes a certification that the applicant is free of such a judgment lien against his/her property.

Delinquency on a Federal Debt

The application also includes a certification that the applicant is not delinquent on repayment of any

APPLICANT ELIGIBILITY (Continued)

Federal debt. A Federal debt includes debts arising from Federal taxes, Federal loans, federally guaranteed or insured loans such as student or home mortgage loans, an overpayment of Federal benefits and any other debt owed to the Federal Government. An applicant is considered delinquent on a Federal debt if he or she has ever been more than 31 days past due on a scheduled payment. Delinquent applicants will not be selected for scholarships regardless of circumstances.

No Conflicting Service Commitments

Applicants who are already obligated to a Federal, State, or other entity for professional practice or service after academic training are not eligible for NHSC scholarship awards. An exception may be made if the obligating entity provides documentation that there is no conflict in fulfilling the service commitment to the NHSC Scholarship Program and that the NHSC Scholarship Program service commitment will be served first.

A scholarship recipient who meets the above exception should not expect to be assigned for service in a State, community, or medical facility to which the recipient already owes a commitment for service. The national staffing needs of the NHSC preclude any such advance placement commitments to NHSC Scholarship Program recipients.

Scholarship recipients, except military reservists, who subsequently enter other service commitments, or who otherwise are not immediately available after completion of their degrees or authorized deferments to fulfill their scholarship service commitments, will be subject to the breach-of-contract provisions described later in this *Bulletin*.

Members of a Reserve Component of the Armed Forces

Individuals in the Reserve component of the Armed Forces or National Guard are eligible to participate in the NHSC Scholarship Program. However, reservists should understand the following:

First, the placement opportunities for reservists may be limited by the NHSC, in order to minimize the negative impact that a deployment would have on the vulnerable populations served by the NHSC. For example, the NHSC would not approve placement of a reservist as the sole provider at a clinic that would be forced to close if the reservist were deployed.

Second, military training or service performed by reservists will not satisfy the NHSC service commitment. If a participant's military training and/or service, in combination with the participant's other absences from the service site, exceed 7 weeks (49 calendar days) per service year, the NHSC service commitment end date will be extended to compensate for the break in NHSC service. See discussion of "Full-Time Clinical Practice" on page 15 of this *Bulletin*.

Third, if the site where the reservist was serving at the time of his/her deployment is unable to re-employ that reservist (because re-employment would be impossible or unreasonable), the NHSC will reassign the participant to another service site to complete his/her remaining NHSC service commitment. In some cases, a participant may be asked to sign an employment contract, which extends beyond the completion date of his/her NHSC service commitment.

SUBMITTING THE APPLICATION

In order to be eligible for an NHSC scholarship award, the documentation mentioned below must be received by the NHSC or be postmarked on or before the following deadlines. ***No extensions on the following deadlines will be granted.***

- **Application with Supporting Documents**

  The deadline for receipt of the NHSC Scholarship Application for Participation is **March 26, 2004.**

- **Verification of Acceptance/Verification of Good Standing**

  The deadline for submitting the verification of acceptance/verification of good standing report or letter is:

  - *March 26, 2004, for allopathic, osteopathic and dental students; and*
  - *July 1, 2004, for family nurse practitioner, nurse-midwife, and physician assistant students.*

- **Authorization to Release Information Letter**

  The deadline for submitting the Authorization to Release Information Letter is **March 26, 2004,** for all NHSC scholarship applicants.

Applicants are encouraged to submit their applications as early as possible. Early submission allows the program to review applications and send out notification letters identifying any missing documents. The notification letters will afford the applicant the opportunity to submit any missing documents and/or make any necessary corrections to his or her file, prior to the applicable deadlines. The NHSC Scholarship Program will stop mailing notification letters two weeks prior to the March 26, 2004 deadline.

SUBMITTING THE APPLICATION (Continued)

Verification of Acceptance/Verification of Good Standing

No applicant will receive an award unless and until he or she is enrolled or accepted for full-time enrollment in a fully accredited program during the 2004-2005 school year (applicant must begin classes on or before January 2, 2005). Each applicant is required to submit a report or letter verifying his or her acceptance or good standing from the program within the established deadlines set forth in this *Bulletin*. Applicants are encouraged to use the Verification of Acceptance Report or the Verification of Good Standing Report in the back of this *Bulletin*. The verification reports **must bear the training institution's raised seal.** If a letter is submitted in lieu of the reports, the letter must be on the school's letterhead, bear the training institution's seal, and address each of the 10 items outlined on page 19 of this *Bulletin*, under "General Directions" paragraph 2 "Verification of Acceptance/ Verification of Good Standing."

Applicants who have not been accepted for enrollment at the time of submitting the application must indicate on the application only one school or program they anticipate attending, and the verification of acceptance letter or report must be received by the established deadline.

If the applicant's choice of school changes, the applicant must notify the NHSC Scholarship Program in writing and submit a verification of acceptance/verification of good standing report or letter from the new school.

If the applicant's choice of program/discipline changes, the applicant must notify the NHSC Scholarship Program in writing and submit a verification of acceptance/verification of good standing report or letter from the new program.

All school and discipline changes must be submitted by July 1, 2004. If the school or discipline change is submitted after July 1, 2004, the NHSC Scholarship Program may not have the scholarship funds to pay for an increase in the tuition, fees and other reasonable educational costs for a school not indicated on the Original Notice of Award Letter issued by the Program.

If the verification of acceptance/verification of good standing report states that there are conditions (not yet fulfilled) for acceptance into the school and/ or program, applicants will not be eligible for consideration for an award for the 2004-2005 school year, unless all contingencies or conditions for acceptance are removed in writing by the school prior to the applicable deadline for enrollment verification.

All documentation must be received in our office or be postmarked by the applicable deadline. FAXES OR PHOTOCOPIES ARE NOT ACCEPTABLE.

Using Current Application Packet

Application packets may be obtained from the NHSC Scholarship Program, c/o IQ Solutions, 11300 Rockville Pike, Suite 801, Rockville, MD 20852, telephone: 800-638-0824. Also, application packets for 2004-2005 scholarship awards may be obtained from the financial aid or program director's office serving any fully accredited medical and dental schools, family nurse practitioner, nurse-midwifery, or physician assistant program in the United States.

Students who have submitted applications to the NHSC Scholarship Program in past years and who did not receive or accept an award must complete a new application and compete with all other applicants.

SELECTION CRITERIA AND FUNDING PRIORITIES

The NHSC Scholarship Program for the 2004-2005 school year is very competitive; the Program anticipates more applicants for scholarship awards than there are funds available. Students are advised to apply for other funding sources also, due to the competitiveness of the NHSC Scholarship Program.

This section describes the factors that will be considered in approving applications for participation in the NHSC Scholarship Program.

The Personal Interview

The applications of individuals who meet the eligibility criteria are scored numerically. Where the application scores fall within the competitive range, the applicants will be invited to have a personal interview. Applicants will be notified by mail of dates, times and locations of the interviews.

Applicants who do not meet the eligibility criteria or whose scores do not fall within the competitive range will not be invited for an interview and will be notified of non-selection.

The interviewers ***cannot*** guarantee any practice site opportunities or selection preferences.

Selection Criteria

The NHSC Scholarship Program will consider well-prepared applicants who demonstrate geographic flexibility and a strong interest in providing primary health

SELECTION CRITERIA AND FUNDING PRIORITIES (Continued)

care to the underserved populations nationally, based on information provided in the application and during the interview. Please remember that all applicants who demonstrate a high potential for providing quality primary health care may not receive a scholarship award due to limited funding.

Applicants who do not demonstrate a high potential for providing primary health care in designated shortage areas will not be selected for a scholarship award.

Funding Priorities for the 2004-2005 Academic Year

Applications and interviews that demonstrate the applicant's high potential for providing primary health care services will be competitively evaluated and scored. The following statutory priorities for funding will be applied:

FIRST PRIORITY

A. Former NHSC Scholarship Recipients

Former NHSC Scholarship Program recipients who are seeking support for the 2004-2005 academic year, or through their date of graduation;

B. Recipients of Federal Scholarship Program for Students of Exceptional Financial Need (EFN) (Medical Students Only)

Applicants who have received a Scholarship for Students of Exceptional Financial Need under former section 736 of the PHS Act (42 U.S.C. 293) qualify for a funding priority. Applicants claiming EFN status must submit by **March 26, 2004**, written documentation from their school's financial official of their current or former participation in the EFN Program.

SECOND PRIORITY

Applicants with HPSA Retention Characteristics

Applications and interviews will be scored numerically based on the extent to which the applicants appear to have characteristics that increase the probability they will continue to practice in HPSAs after they have completed their service commitments. These characteristics include:

(a) Strong primary care post-service career goals in HPSAs;

(b) Experience within indigent or underserved communities;

(c) Understanding and acceptance of the mission of the NHSC; and

(d) Intent to participate in pre-professional clinical experiences in rural or urban community-based health care facilities serving HPSAs. Settings for such experiences may include community health centers, migrant health centers, Indian Health Service Centers and Hospitals, Bureau of Prisons health facilities, AIDS outpatient clinics, drug abuse treatment centers, clinics for the homeless, or family practice clinical settings outside of a hospital.

THIRD PRIORITY

Applicants From Disadvantaged Backgrounds

Applicants who have the HPSA retention characteristics and who also are certified as having come from "disadvantaged backgrounds" will be selected for awards before those who are not certified as disadvantaged.

(a) *For Medical and Dental Students:* Applicants' schools must certify that the applicants participated in, or would have been eligible for participation in, Federal programs such as "Scholarships for Disadvantaged Students" and "Loans to Disadvantaged Students."

(b) *For Nursing and Physician Assistant Students:* Their schools must certify that the applicants participated in, or would have been eligible for participation in, Federal programs such as "Scholarships for Disadvantaged Students" or the benefits of the "Nursing Workforce Diversity Grants."

Applicants who wish to claim "disadvantaged background" should submit with their applications a written statement from the student financial aid administrator certifying their participation in, or eligibility for participation in, a qualifying Federal program.

For information about programs for disadvantaged students, visit the website http://www.bhpr.hrsa.gov/dsa/weblinks.

Notification of Selection/Acceptance of Award

Individuals selected for awards (selectees) will be notified by letter, as early as August 1, 2004, and no later than September 30, 2004. Information on how to obtain the Direct Deposit and W-4 forms will be provided in the notice of award letter. **To accept this award, no later than 15 days from the date of receipt of the notice of award letter, the selectee must submit completed and signed Direct Deposit and W-4 forms to the NHSC Scholarship Program (faxes are acceptable).** ***If the completed Direct Deposit and W-4 forms are not received by the NHSC Scholarship Program within 15 days of the selectee's receipt of the notice of award letter, the offer of award terminates, and the award will be offered to an alternate.***

Individuals selected for an award must attend classes during the 2004-2005 school year and that

SELECTION CRITERIA AND FUNDING PRIORITIES (Continued)

class attendance must begin on or before January 2, 2005. Individuals, whose class attendance during the 2004-2005 school year will begin after January 2, 2005, MUST decline the award. **Please note that the ranking of selectees *will not* be disclosed.**

Notification of Alternate Status

Individuals selected as alternates will be notified by letter, as early as August 1, 2004, and no later than September 30, 2004. Alternates will be notified of selection as selectees decline their awards. **Please note that the ranking order of alternates *will not* be disclosed.**

Notification of Non-Selection

Individuals whose application and interview scores did not fall within the competitive range to be considered as an NHSC scholarship awardee or alternate will be notified no later than September 30, 2004.

Declining Scholarship Support

Selectees may decline awards without penalty (permitting the promotion of alternates to selectee status) by:

(1) failing to submit completed and signed Direct Deposit and W-4 forms to the NHSC Scholarship Program within 15 days of receipt of the notice of award or

(2) mailing or faxing a signed letter declining the award offer, with the reason for declination, to the NHSC Scholarship Program within 15 days of receipt of the notice of award letter. ***Telephone declinations will not be accepted.***

Once a selectee declines the offer of award, the award will be offered to an alternate. ***There will be no opportunity to reclaim the award.*** **A decision to decline the scholarship award is final and *cannot* be changed *under any circumstances*.**

Further details about awards may appear in a transmittal memorandum enclosed with the application packet.

SCHOLARSHIP BENEFITS

The NHSC Scholarship Program financial benefits depend on the availability of funds appropriated by the Congress of the United States and approved by the President for the 2004 fiscal year.

Awards Limited to 4 School Years

Scholarship awards will be granted for no more than 4 school years which includes any partial year of funding received during the school year. All awards to students (including students in Family Nurse Practitioner, Nurse Midwifery, and Physician Assistant Programs) are based on a 1-year, 12-month period. The school year is defined as July 1 through the following June 30. Students ***may not*** receive full funding for each school year of their program, to the extent their course work does not coincide with the NHSC Scholarship Program's definition of school year. (For more information, see section "Graduating Off-Cycle" in this *Bulletin*).

Commencement and End of Scholarship Support

Participation in the NHSC Scholarship Program becomes effective when the Director, DNHSC (the designee of the Secretary of Department of Health and Human Services) signs the applicant's contract.

New applicants must be able to financially support themselves until the first week of November. **The first scholarship payment should be received in the applicant's banking account by the 7th of November. The end of scholarship support will be the month that the scholar completes the required classes for graduation or June 30, whichever comes first.** The NHSC Scholarship Program ***cannot*** make payment to scholars when they are not enrolled or attending classes on a full-time basis.

Distance Learning Programs

Individuals who are participating in distance learning programs are advised that they ***may not*** receive full funding for each year of their program, to the extent that their course work does not coincide with the NHSC Scholarship Program's definition of school year (running from July 1 through June 30). Also, the NHSC Scholarship Program ***will not*** pay for any penalty or additional distance learning fees that are incurred for not completing your course load in the required time frame.

Payment of Tuition & Required Fees

The NHSC Scholarship Program will pay tuition and required fees directly to the school, subject to limitations set forth below.

The NHSC Scholarship Program will not pay for any increased tuition rates or required fees for the year that may be reported by the school after June 6, 2004. The program will not pay tuition and fees for any portion of a school term prior to July 1, 2004. If a recipient

SCHOLARSHIP BENEFITS (Continued)

changes schools, the recipient must notify the NHSC Scholarship Program in writing and submit another report or letter verifying acceptance from the new school by July 1, 2004. See section "Verification of Acceptance/Verification of Good Standing" on page 5 of this *Bulletin*.

The NHSC Scholarship Program will not pay for tuition costs unrelated to the degree program, penalty fees for over extension of a distance learning program, or for membership dues for student societies, associations, loan processing fees, and similar expenses. **Also, the NHSC Scholarship Program will pay *ONLY* for courses that are required for graduation. Elective courses, which are not a requirement for graduation, are not eligible for payment.** If an applicant is unsure of what is covered by the NHSC scholarship, please contact the NHSC Scholarship Program in writing for further clarification.

Upon receipt of an invoice for the tuition and fees required of all students, any fees on the invoice that were included in Other Reasonable Cost will not be approved for payment, as those funds are provided separately and paid directly to the scholar. ***Please be advised that under the Debt Collection Improvement Act of 1996, all Federal payments must be processed through Electronic Funds Transfer/Direct Deposit. Therefore, all educational institutions must have an electronic funds transfer account with our Division of Financial Operations (DFO) in order for tuition and fee payments to be made in a timely manner.***

Receipt of an NHSC scholarship award does not automatically preclude a participant from receiving funds from other programs, as long as no service commitment is involved. However, many student assistance programs are based on the student's financial need, or may be limited to the payment of expenses already paid by the NHSC Scholarship Program. The list of NHSC Scholarship Program recipients supplied to the schools will enable the school officials to reevaluate the financial need or eligibility of these individuals for funds under other aid programs. When continuation of financial assistance is not warranted, the school is required to reduce or terminate payments. Applicants should contact their financial aid officers to determine how the receipt of an NHSC scholarship may affect them.

Other Reasonable Costs (ORC)

The NHSC Scholarship Program will make ORC payments to include expenses for required books, clinical supplies, laboratory expenses, instruments, two sets of uniforms, graduation fees (if applicable), computer/PDA rental or purchase (only if required of all students) and travel expenses for one clinical rotation. The ORC is based on estimated cost submitted by the educational institution. For new awardees, the ORC will be paid with the first stipend payment (received by the first week of November). The ORC payment covers the school year and the student must budget funds received accordingly.

The payment made to the scholarship recipient may or may not meet the total expenses required by the school.

Individual vouchers or receipts for expenses will not be honored.

Stipend Amount

During the 2004-2005 academic year, the NHSC Scholarship Program will pay a stipend of $1,065 **(before Federal taxes)** directly to each recipient at the end of each month. The first payment for new awardees will include the stipends retroactive to July 1, if the scholar has started classes on or before January 2, 2005, and the payment for Other Reasonable Costs.

Receipt of the monthly stipend payment does not mean that the student is employed by the Federal Government or participates in any of the benefits available to Federal employees.

Method of Payment

DIRECT DEPOSIT IS MANDATORY. All stipend and Other Reasonable Cost payments are paid directly to the student's financial institution through direct deposit. Information about how to obtain the direct deposit form (Standard Form 1199A) will be included in the Notice of Award Letter for new scholarship recipients. ***Any change in financial institution or account information will require submission of a new direct deposit form. Do not close the old account until the first payment in the new account is received to insure that there is no delay in payment.***

Taxation of the NHSC Scholarship

ONLY THE MONTHLY STIPEND PAYMENTS made to scholars under the NHSC scholarship are taxable.

Information on how to obtain an Internal Revenue Service (IRS) Form W-4 will be provided to new scholarship recipients with the Notice of Award Letter for the 2004-2005 academic year. The information provided on the W-4 form will be used to determine withholding of Federal taxes on the stipend portion of the scholarship. Students who want additional funds deducted from the stipend amount should indicate the additional amount to be deducted on the appropriate line on the W-4 form. We advise students to consult their local tax authority regarding State or local taxes for which they may be liable, as State and local income taxes will not be withheld. **It is the responsibility**

FULFILLING THE SERVICE COMMITMENT (Continued)

(OPP) to suspend their service commitments for up to 1 year. Such requests must be in writing and include a detailed written explanation and supporting documentation, as required by the OPP. See the "Waiver, Suspension or Cancellation of the Commitment," section in this *Bulletin*.

Ending Date of Obligated Service

The last day of the service commitment is determined in whole years from the starting date. For example, the last day of service for a recipient with a 3-year service commitment who began service on July 15, 2003, would be July 14, 2006. Adjustments in the ending date may be made by the NHSC if the scholar takes more than the allowable time away from the site (see "Full-Time Clinical Practice" section) and if the commitment is suspended, interrupted, or otherwise delayed.

NOTE: Please be advised that NHSC scholarship recipients will not be given preference if they decide to apply for the NHSC Loan Repayment Program after they have completed their scholarship service commitment.

Service Assignment Process

NHSC Scholarship Program recipients must fulfill their service commitments at approved sites in federally-designated HPSAs with the greatest need at the time of assignment, as determined by the Secretary (or designee). These may include placements to the Indian Health Service (IHS), the medical facilities of the Federal Bureau of Prisons (BOP), or the Immigration Health Service.

NHSC scholarship recipients cannot fulfill their NHSC Scholarship Program service commitments by serving in one of the Armed Forces of the United States or the Veterans Administration.

Approximately 1 year prior to the scheduled start of service for physicians and dentists, the NHSC will send recipients information about the placement process for that year. The other health professionals will be sent information about the placement process for that year approximately 4 months prior to the scheduled start of service. The packet will include the Approved Practice List containing job vacancies for which scholars in each discipline and specialty can compete.

There is no guarantee that HPSAs or sites which are currently approved for NHSC placements will still be approved at the time applicants are available to serve.

Recipients who fail to obtain a placement in one of the approved practices by the deadlines announced by the NHSC will be assigned to a practice by the DNHSC. Recipients who, for any reason, fail to begin or complete service at their assigned service location breach the NHSC Scholarship Program contract and incur the damages described on page 15, section "Failure to Begin or Complete the Service Commitment or Meet the Terms and Conditions of Deferment" in this *Bulletin*.

The NHSC reserves the right to make final decisions on all placements, in order to comply with statutory requirements for the placement of scholarship recipients.

Types of Placements

The following types of NHSC placements may appear on the Approved Practice List:

- **Non-Federal Placements:**
  - *Private Practice Assignment (PPA)*

    A PPA is an assignment to a public or private entity that operates a community-based system of care where a scholar may serve his/her commitment. These entities may be supported by local communities or may be supported in part by Federal grant funds. Under the PPA, scholars are considered non-Federal members of the NHSC and are paid by and work under the personnel system of the entity to which they are assigned. The salary and benefits paid by the entity must be at least equal to the salary and benefits that the scholar would have received as a Federal civil service employee. Malpractice insurance should be agreed upon by the employer and the scholar and detailed in a written contract. The NHSC requires that each entity make provisions for malpractice insurance, including tail coverage, for scholars under the PPA.
  - *Private Practice Option (PPO)*

    A PPO is a release (from having to serve as a member of the NHSC) to serve in a private practice that operates as fee-for-service, or a salaried position at a public, private non-profit or for-profit site. There is no minimum provider salary and benefit package requirement for a PPO. If a PPO placement is approved by the NHSC, the scholar must sign an agreement to, among other things; comply with the section "Charges for Services" requirements set forth in this *Bulletin*. The scholar must also prepare and submit a Uniform Data System report to the NHSC on the conduct of his/her practice. **NOTE:** PPO providers must make arrangements to obtain their own malpractice and medical insurance.

FULFILLING THE SERVICE COMMITMENT (Continued)

- **Federal Placements:**

  – *Indian Health Service (IHS)*

  This agency offers a variety of placement opportunities at hospitals and other health care facilities serving Native American populations (usually on Indian reservations).

  – *Federal Bureau of Prisons (BOP)*

  This agency of the Department of Justice employs health professionals in Federal prison facilities ranging from infirmary-size units to 500-bed tertiary care hospitals throughout the United States. This placement requires a security clearance and background check.

  – *Division of Immigration Health Services of the Immigration and Naturalization Service*

  This Agency provides primary health care for the detainees remanded to the custody of the U.S. Immigration and Naturalization Service. There are currently eleven Service Processing Centers throughout the country and within each center there is a fully accredited outpatient clinic. This placement requires a security clearance.

Charges for Services

Federal and PPA entities, as well as PPO providers, must not discriminate in the provision of Services to an individual because that individual is unable to pay or because payment would be made under Medicare, Medicaid or the State Children's Health Insurance Program. A schedule of discounts (including, in appropriate cases, waiver) must be utilized for patients unable to pay. Finally, Federal and PPA entities and PPO providers must accept assignment under Medicare and enter into appropriate agreements with State agencies to participate in the Medicaid and State Children's Health Insurance Programs.

Licensure/Certification Required

Scholarship recipients ***must be permanently licensed in their scholarship-supported profession*** **prior to commencing service.** Credit towards fulfillment of the scholarship commitment will not be given in the absence of a current, unrestricted permanent license.

Scholarship recipients serving under a PPO or PPA Agreement are required to have a license in the State where the practice site is located. Scholarship recipients serving as Federal employees are required to be licensed in a State. Responsibility for obtaining the required State license prior to the service start date rests with the scholarship recipient. Given that scholars will be required to serve in the areas of greatest need throughout the country, each scholar is responsible for ensuring that his or her professional program and licensing exam will provide broad eligibility to obtain a license in multiple States.

Physicians

All physicians must have successfully completed Steps 1, 2 and 3 of the United States Medical Licensing Examination (USMLE) or Levels 1, 2, and 3 of the Comprehensive Osteopathic Medical Licensing Examination (COMLEX) by the time they complete their primary care residency training program. To assure that physician scholars are able to fulfill their commitment wherever the need is greatest upon completion of their primary care residency, the NHSC expects all MD/DO scholars to take and pass:

- ➢ Step 1 of the USMLE or Level 1 of the COMLEX by the end of the 2nd year of their MD/DO program.
- ➢ Step 2 of the USMLE or Level 2 of the COMLEX by the end of the 4th year of their MD/DO program.
- ➢ Step 3 of the USMLE or Level 3 of the COMLEX by the end of the 1st year of their post-graduate (residency) training program.

MD/DO scholars unable to pass all parts of the licensing examination and obtain a license to practice medicine by the time the service is scheduled to begin will not be routinely eligible for a suspension of their service obligation and may be placed in default.

Dentists

All dentists must have successfully completed the National Board Dental Examination Parts 1 and 2 prior to beginning their NHSC service. To assure that dentists will have licensure in States with the greatest dental needs, the NHSC reserves the right to determine which Regional or State clinical exam the dental scholar should take and pass. Dental scholars are expected to take the appropriate exams at the earliest possible date. If the recipient is unsuccessful in passing the exams and obtaining a license, the recipient should immediately contact the Legal and Compliance Branch, in writing, to request a suspension. Please see the "Waiver, Suspension or Cancellation of the Commitment" section in this *Bulletin*.

Nurse Midwives, Family Nurse Practitioners and Physician Assistants

All nurse midwives, family nurse practitioners and physician assistances must have successfully completed national certification exams for their disciple prior to

FULFILLING THE SERVICE COMMITMENT (Continued)

beginning their service commitments. Students are expected to take the appropriated certification exam at the earliest possible date. No service credit will be given to any NHSC scholar for practice at an NHSC site prior to passing the national certification exams. If the recipient is unsuccessful in passing the national certification exam, the recipient should immediately contact the Legal and Compliance Branch, in writing, to request a suspension. Please see the "Waiver, Suspension or Cancellation the Commitment" section in this *Bulletin*.

"Full-Time Clinical Practice"

By law, NHSC scholars must be engaged in the full-time clinical practice of their discipline/specialty at the HPSA practice to which they are assigned. The NHSC defines a full-time clinical practice as a minimum of 40 hours per week, for a minimum of 45 weeks per year. The 40 hours per week may be compressed into no less than 4 days per week, with no more than 12 hours of work to be performed in any 24-hour period. The practice will include hospital treatment coverage appropriate to meet the need of patients and to ensure continuity of care. For all health professionals except obstetrician/gynecologists, family practice physicians who continuously provide obstetrical services and certified nurse-midwives, **at least 32 of the minimum 40 hours per week must be spent providing clinical services in the ambulatory care setting** at the approved practice site during normally scheduled office hours. Obstetrician/Gynecology physicians, certified nurse-midwives, and family practice physicians who continuously provide obstetrical services, are required to engage in a minimum of 21 hours per week of outpatient clinical practice, in addition to deliveries and other inpatient coverage. For all health professionals, time spent "on call," teaching, research or other non-clinical duties do NOT count toward the required 40 hours/week.

Work schedules at Federal facilities may be significantly different than community-based systems of care. Scholars who are interested in practice positions at Federal facilities need to discuss the details with these facilities directly.

DEFAULTING ON THE SCHOLARSHIP COMMITMENT – BREACH OF CONTRACT

Failure to Complete Academic Training

Scholarship recipients who are dismissed from school for academic or disciplinary reasons, or who voluntarily terminate academic training before graduation from the educational program for which the scholarship was awarded, will be declared in breach of their scholarship commitment and held liable to the United States for repayment of ***all NHSC Scholarship Program funds paid*** to them and to the school on their behalf. The amount owed must be paid in full within **3 years of the date of default.** No interest will be charged on any part of this debt to the United States during the 3-year repayment period. However, if payment in full is not made within the 3-year period, interest will be assessed thereafter.

Failure to Begin or Complete the Service Commitment or Meet the Terms and Conditions of Deferment

Scholarship recipients who, for any reason, fail to comply with the terms and conditions of deferment (including physicians who fail to complete an NHSC-approved residency) or who, for any reason, fail to begin or complete their service commitments after completion of training, will be in breach of their scholarship commitments. When recipients breach for these reasons, the United States shall be entitled to recover damages equal to ***three times the scholarship award plus interest***, in accordance with the formula:

$$A = 3\text{Ø}\left(\frac{t-s}{t}\right)$$

In which:

'**A**' is the amount the United States is entitled to recover,

'**Ø**' is the sum of the amounts paid to or on behalf of the participant and the interest on such amounts which would be payable if, at the time the amounts were paid, they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States,

'**t**' is the total number of months in the participant's period of obligated service, and

'**s**' is the number of months of the period of obligated service served by the participant.

The damages which the United States is entitled to recover shall be paid within **1 year of the date of default.**

Delinquent Debt

If the debt is not repaid within 1 year or 3 years (as applicable), and subsequent collection efforts are unsuccessful, the case will then be referred to the Department of Justice for litigation. The recipient will be liable for the debt incurred plus administrative costs and court costs associated with collection of the debt.

ATTACHMENT J

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE
WORKGROUP ON COMPOUNDING
Meeting Summary

DATE: March 3, 2004

TIME: 1:30 p.m. – 4:00 p.m.

LOCATION: Holiday Inn Oakland Airport
500 Hegenberger Road
Oakland, CA 94621

Workgroup Members: Ken Schell, Pharm.D., Chair
John Tilley, R.Ph.

Staff Present: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Dennis Ming, Supervising Inspector
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Paul Riches, Chief of Legislation/Regulation
Joshua Room, Deputy Attorney General

Call to Order/Introductions

Chair of the workgroup, Dr. Schell, called the meeting to order at 1:30 p.m. Individuals attending the meeting were all invited to participate and were asked to introduce themselves.

Purpose of the Workgroup

Dr. Schell explained that the Board of Pharmacy originally formed this workgroup at the request of the Department of Health Services, State Food and Drug Branch (FDB). The FDB is responsible for licensing California's drug manufacturers and asked the board to clarify the criteria it uses to determine when pharmacy compounding falls outside the scope of pharmacy practice. Dr. Schell also stated that it is the board's goal to identify "gaps" in pharmacy law related to compounding and to address them. The purpose of the workgroup is for the board to work with the profession to identify compounding issues, gaps in pharmacy law and to the extent possible seek solutions.

Federal Food and Drug Administration (FDA)
COMPLIANCE POLICY GUIDES – Sec. 460.200 – Pharmacy Compounding

Fred Richman and Kathy Anderson from the FDA Center for Drug Evaluation and Research participated in the workgroup discussion via telephone. They answered questions regarding the May 2002 compliance guide that was issued regarding pharmacy compounding. The document provides guidance to pharmacies and the staff of the FDA on how the FDA addresses pharmacy compounding of human drugs as a result of the decision of the Supreme Court in Thompson v. Western States Medical Center, No. 01-344, April 29, 2002.

As they indicated, the FDA generally defers to state authorities with regard to the day-to-day regulation of pharmacy compounding of human drugs. FDA recognizes that pharmacists traditionally have compounded human drugs upon receipt of a valid prescription for a patient from a licensed practitioner. This traditional activity is not the subject of the compliance guide.

What concerns the FDA are pharmacies that are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is outside the bounds of traditional pharmacy practice. FDA is concerned that some pharmacies are involved in large scale compounding that is essentially manufacturing. It was explained that while all compounded drugs are "unapproved" new drugs by FDA law, FDA recognizes the need for extemporaneous compounding, in reasonable quantities, upon a valid prescription order to meet individual patient needs and where appropriate, FDA exercises its enforcement discretion. The FDA's primary responsibilities are to protect the public health and that may be jeopardized when there is large scale pharmacy compounding. As the volume of compounding increases so does the public's exposure to potential problems. Pharmacies are not subject to the New Drug Application (NDA) process and Good Manufacturing Practices (GMPs) required of manufacturers. These requirements are important to ensure the safety and effectiveness of the drug.

Representatives from FDA stated that the agency is working on revising the guidelines and plans to have a public meeting to discuss pharmacy-compounding issues.

Overview of Pharmacy Law Related to Compounding – Application of USP 797

Supervising Inspector Dennis Ming identified the pharmacy law that regulates compounding. He stated that the proposed amendments to California Code of Regulations, title 16, sec. 1751-1751.12, were adopted by the Board of Pharmacy at its meeting in October. He stated the regulations are going through review by the Administration and should be filed with the Office of Administrative Law (OAL) in the near future. The proposed regulations govern the compounding of injectable sterile drug products.

There were questions as to how the recently approved U.S. Pharmacopeia (USP) General Chapter 797 on pharmaceutical compounding of sterile preparations affect California pharmacy practice and the pending regulations. USP Chapter 797 provides procedures and requirements for compounding preparations. It is intended to be applicable to health care institutions, pharmacies, physicians practice facilities, and other facilities where compounded sterile preparations are prepared, stored and dispensed. Many of the participants were of the opinion

that USP 797 has the same force of law and may void the board's pending regulations if the USP requirements are more restrictive.

It was explained that during the development of the proposed regulations on sterile compounding of injectable drug products, the board was unable to find any legal reference that adopted USP 797 as federal or state law. Many disagreed with this statement and offered to provide the federal and/or state law that recognizes the USP standards as law.

Identification of Compounding Issues

The workgroup identified compounding issues that they felt that the Board of Pharmacy should address. The workgroup identified the issues, classified them and then workgoup members volunteered to develop suggestions to address the issues. When developing the proposals, various references were suggested such as USP, FDA requirements and compliance guides, professional association guidelines, NABP's model laws and other states' requirements.

LAW

- Manufacturing/Compounding
- Efficacy
- OTC Compounding
- Veterinary Compounding
- Definition of Compounding
- Anticipatory Compounding
- Central Fill for Compounding
- Label on "unit of use" containers

Workgroup Members: Dan Wills, Wayne Vega, Mike Koch, Bill Blair

Quality Standards

- Non-sterile Compounding (USP 795/1075)
- Equipment Quality/Process Validation

Workgroup Members: Steve Feldman, Helen Chang, Chuck Leiter, Joe Grasela

Sterile Compounding

- Clarification of USP 797 and impact on California regulations on compounding of sterile injectable drug products
- Environmental Control of sterile compounding
- Clarification of state/federal definition of inhalation drugs, otics, and ophthalmic
- Oils/Suspensions – Appropriate Sterilization Process

Separation of Sterile vs. Non-sterile Compounding Process

Prioritization of Issues and Assignments

Dr. Schell requested that the workgroup members that volunteered to work on the various issues do so in-between meetings. It was also noted that the workgroup would not be addressing the

issue of sterile compounding of injectable drug products since the board has adopted regulations in this area. All proposals that are to be considered by the workgroup should be sent in at least two weeks before the next workgroup meeting. The proposals will then be shared with the group in advance of the meeting.

Future Meeting Dates

Dr. Schell stated that the Workgroup on Compounding Issues will meet as needed after the Licensing Committee. The dates are: June 9th (Burbank), September 22nd (Oakland) and December 1st (Burbank).

Adjournment

Dr. Schell thanked the participants for attending and adjourned the meeting at 4:00 p.m.

ATTACHMENT K

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE: March 3, 2004

TIME: 9:30 a.m. – 12 noon

LOCATION: Holiday Inn Oakland Airport
500 Hegenbeger Road
Oakland, CA

BOARD MEMBERS Clarence Hiura, Pharm.D., Chair
Ruth Conroy, Pharm.D.
John Tilley, R.Ph.

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Paul Riches, Legislation Chief
Dana Winterrowd, Staff Counsel

Call to Order

Committee Chair Clarence Hiura called the meeting to order at 9:30 a.m. He explained that committee member Richard Benson would not be attending the meeting because of another commitment. He noted that he would not be attending the Board meeting in April and Ruth Conroy agreed to present the Licensing Committee report.

Report on the Implementation of the North American Pharmacy Licensure Examination (NAPLEX) and the California Specific Examination

Assistant Executive Officer Virginia Herold reported that the board is still waiting for the Department of Consumer Affairs and the Department of General Services to approve the contracts needed to implement the NAPLEX and CPJE in California. It is believed that both contracts are in the final stages of approval.

The board's goal has been to have applicants able to take both the CPJE and NAPLEX, with California as the qualifying state, in March. However, this will depend on when the contracts are finally signed. Both exams will be available six days a week at designated testing locations across the United States. There will be 125 sites for the CPJE.

The board has 611 applicants for the exams as of today. There were 141 applications received before July (most of these individuals postponed taking the June examination), and 470 have been received since July 1.

Application forms and instructions detailing the application process are available on the board's Web site. A Candidates' Guide handbook detailing procedures for taking the CPJE, what to expect at the test site, and how to study for the CPJE (including sample questions) has been developed. The board will place this handbook on its Web site, but Experior Assessments (the test administrator) will send a handbook to each candidate who has been qualified by the board to take the CPJE.

The NABP has a handbook containing similar information on its Web site regarding the NAPLEX that is available for downloading by applicants. Ms. Herold emphasized the changes to the security requirements for admissions to the CPJE examination. Applicants are required to bring a government-issued identification (driver's license, state-issued identification card, military card) containing a recent photograph and a federal Social Security card. The name appearing on both of these identification cards must match exactly the name used to register for the CPJE, including designations such as "Jr." or "III," etc. If the applicant does not have the appropriate identification, then he/she will not be admitted to take the examination and will need to reschedule.

The CPJE has been tested online and is ready to go. The computer administration is very basic and individuals without computer experience (which is very unlikely for pharmacists) can still take the examination online without even typing knowledge. A tutorial will be given at the test site for each applicant before he or she starts the examination.

The board will release examination results within 15 days following the NAPLEX and approximately 30 days following the CPJE.

The board has made proposed regulation changes to its examination procedures to fully implement the NAPLEX and CPJE. The regulations have been noticed and the board will act on them at the April meeting.

Proposal to Restructure the Competency Committee

Ms. Herold reported that the board's Competency Committee has created, overseen the administration of, and graded the California pharmacist licensure examination. Until January 2004, the examination was given twice a year and was comprised of 300 multiple-choice items and a 100-point, short-answer examination that had to be hand-graded.

This year, under the new examination structure created by SB 361, the board still must develop one examination, the 90-item multiple-choice CPJE. However, to prevent exam compromise, many more than 90 questions are being administered at any time. The Competency Committee develops these questions.

Appointment to the committee is an honor, but the work required of the committee is demanding. There is a minimum of seven two-day meetings annually, and additional outside time spent writing questions. Additionally, there are periodic subcommittee meetings to review performance statistics of the examination or perform other specialized tasks. Whereas the committee formerly hand-graded the short answer exam (this accounted for two of the seven two-day meetings), the committee is currently creating new items for the new examination structure.

Later this year, the committee will oversee a job analysis of the pharmacist profession; a survey of 2,000 pharmacists for each duty they perform and the importance of each task. From this job analysis, the committee develops the content outline for the examination. This job analysis must be conducted every three to seven years, to assure that the exam remains valid for entry-level pharmacist practice.

The committee is carefully structured to ensure a balance of practitioners from all practice settings. In the last six months, there have been a number of changes as some members have rotated off the committee (they typically serve for eight years) and several others have resigned early due to other commitments. The current composition of 21 members is:

Schools of Pharmacy
- 1 active member UCSF
- 1 active member UOP
- 1 inactive member UOP
- 1 active member Western
- 2 active members USC

Board of Pharmacy
- Ken Schell
- Supervising Insp. Ming & Inspector Janice Dang

Community setting
- 5 active pharmacists
- 1 inactive pharmacist
- 2 vacancies

Inpatient setting
- 4 active pharmacists
- 1 inactive pharmacist

Managed care
- 1 active pharmacist

Typically the inactive members are those who are unable to attend meetings regularly. Additionally, the new pharmacy schools at Loma Linda and UCSD should be offered the chance to appoint members to the committee. In the past, each school has appointed two members.

Now that the needs of the new exam cycles are established, staff believes it is appropriate to convert to a new structure, a structure similar to the one used by NABP. The proposed structure

would be a two-tier structure, a group of item writers to develop questions for the examination, and the core committee – the group that selects items and refines them for the examination, selects a cut score and oversees issues arising from administration of the examination.

The item writers would meet once annually for an item-writing workshop. Then, throughout the year, assignments to write questions in specific areas of the content outline would be assigned to them. The questions would be sent to the board in a secure manner. There would be no other meeting for this group of individuals.

The core committee would refine and revise the questions submitted by the item writers and review items selected for examinations to assure a balanced exam for any applicant. The committee would establish cut scores and review the performance of questions in the exam pool. When necessary, the members would also write items for the examination. This group would be smaller than the current committee (if the current Competency Committee was fully appointed, there would be 29 members). The proposed structure would be:

Recommended Composition:	19 members
Schools of Pharmacy: 1 member each	6 members
Community Practice:	6 members
Institutional Practice:	5 members
Board Member:	1 member
Inspector:	1 member

Attendance at the meetings would be a requirement, and those who miss a certain number of committee meetings each year would be asked to become item writers because attendance at these meetings would not be necessary. There would continue to be seven meetings annually, but the board's item bank of usable items would grow greatly, facilitating examination administration. At some point in the future (perhaps two years), it could be possible to reduce the number of annual meetings of this group, perhaps to five or six meetings per year.

Terms would be for four years, with reappointment to another four years. The board's president would appoint all members. Appointment would require three letters of recommendation in addition to the applicant's curriculum vitae.

The costs for the new structure ($99,724) would be about the same as the costs for the current structure if 29 members were appointed to the committee and attendance remained at current levels – about 50 percent attending any full two-day meeting ($101,810).

Restructuring the committee would reduce the burden placed on the members of the committee to attend 14 meeting days annually and write questions outside of the committee meetings. It would help prevent member "burn-out." Another benefit of using item writers for new questions would be a broader base of examination questions in the "bank." And as stated earlier, within two years, the committee could reduce its number of two-day meetings from seven to five each year if a large enough item bank exists.

The Licensing Committee recommended that the Board of Pharmacy approved the proposed restructure of the Competency Committee.

Report Requirement of Business and Professions Code Section 4200.1 – Four Attempts to Pass the Pharmacist Licensure Examination

Ms. Herold reported that since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times, are required to take 16 units of education in pharmacy in a school approved by ACPE or by the board before they can retake the examinations. This provision will be repealed January 1, 2005, unless the sunset date for this provision is extended.

The board sponsored this provision to remove a number of applicants from the licensure examination who had repeatedly failed the examination – in fact; there were several applicants who had taken the examination more than 25 times. A major concern was that these individuals were taking the examination only to memorize questions that could be provided to preparation course providers.

The provision itself was modeled after a similar provision enacted for the dental examination.

When the provision was enacted in 1997, the board was also mandated to provide a report to the Legislature after June 1, 2004 and before December 31, 2004 on the effect of this provision in four areas. These areas are:

1. The number of applicants taking the examination and the number who fail the examination for the fourth time
2. The number of applicants who, after failing the examination for the fourth time, apply to take the additional 16 semester units of pharmacy education in California, and the number of these applicants who are accepted into the pharmacy education program.
3. The number of applicants who, after filing the examination for the fourth time, apply to participate in any pharmacy studies program, in or out of California, and the number of these applicants accepted by those programs.
4. To the extent possible, the school and country from which applicants graduated and the comparative pass/fail rates on the examination in relation to the school and country.

At the April 2004 Board Meeting, a copy of this report will be provided for review before it is submitted to the Legislature.

However, since the examination structure itself was greatly altered by last year's SB 361, staff requests that an extension in the sunset date for this provision be made. The reason for this is to allow the board time to evaluate the effect of the provision on the new examination structure. Proposed language was provided.

According to a recent legal opinion prepared by Departmental Counsel Dana Winterrowd, the four-time failure provision still affects those who take the CPJE and the NAPLEX. For those

who have never taken the California licensure examination, they will have four opportunities to take and pass the CPJE and four opportunities to take and pass NAPLEX.

If someone had taken the old examination (before January 1, 2004) and failed it one or more times, these attempts do count when determining the four failures. For example, if someone failed the January and June 2003 examinations, he or she would have two more opportunities to pass the CPJE and two opportunities to take the NAPLEX. Once he or she reach four failed attempts, the individual would need to take the 16 units of pharmacy education before he or she could retake the examination.

Some of the schools that provide the pharmacy coursework are Idaho State and Long Island University. In the past, USC also provided the coursework, but discontinued the program several years ago. None of the other pharmacy schools ever established a course.

Some preliminary data:

EXAM	TOTAL CANDIDATES	FOUR-TIME FAILERS	PERCENT
June 2003	1,284	12	0.9 percent
Jan. 2003	675	15	2.2 percent
June 2002	1,156	6	0.5 percent
Jan. 2002	536	21	3.9 percent
June 2001	1,165	12	1.0 percent
Jan. 2001	601	18	3.0 percent
June 2000	1,065	11	1.0 percent
Jan. 2000	537	14	2.6 percent
June 1999	950	9	0.9 percent
Jan. 1999	508	28	5.5 percent
	8,477	146	1.7 percent
	exam attempts	failed 4-times	

The Licensing Committee recommended that the Board of Pharmacy sponsor legislation to extend the provision that requires an applicant who has failed the board's pharmacist licensure examination to take an additional 16 units of pharmacy education. The provision would be extended until the board's next sunset review in 2006.

Proposed Amendment to CCR, title 16, sec. 1719(a) – Board Approval of Pharmacy Schools Pending Accreditation by the Accreditation Council for Pharmacy Education (ACPE)

At the January 2004 Board Meeting, the board agreed to accept "candidate status" accreditation by the ACPE as meeting sufficient standards for the board to issue an intern license to a student at Lake Erie School of Pharmacy.

This was the second time in one year that the board had to consider accreditation of a new pharmacy school because students were seeking California intern licenses. Both schools had limited accreditation status from the ACPE, which required specific board action to assure they could be issued intern licenses. At the board meeting, staff stated that they would suggest a more permanent resolution to the board.

Internship is an integral part of the pharmacy education of students. State licensing agencies look for ACPE accreditation as a means to assure the students are receiving particular (and approved) educational coursework before an intern pharmacist license is issued. This is especially critical for new schools, where there is only provisional ACPE accreditation (full accreditation will not be given until the first students have graduated from the school).

The ACPE Accreditation Manual, 9th Edition has the following definition of "candidate status:"

> **9.3.2 Candidate**. A new program that has students enrolled but has not had a graduating class may be granted Candidate status. The granting of Candidate status denotes a developmental program, which is expected to mature in accord with stated plans and within a defined time period. Reasonable assurances are expected to be provided that the program may become accredited as programmatic experiences are gained, generally, by the time the first class has graduated. Graduates of a class designated as having Candidate status have the same rights and privileges as graduates of an accredited program.

Therefore, staff recommended that the committee consider amending section 1719 regarding the requirements for the admission to the examination to include a school of pharmacy that is accredited or has been "granted" candidate status by the ACPE.

The committee noted that section 1719 relates to the requirements for admission to the pharmacist licensure examination. It does not address the requirements for the issuance of an intern permit. While this section needs to be updated, staff would review the intern sections to include the same provision.

The Licensing Committee recommended that the Board of Pharmacy revise section 1719 and other "intern" provisions to recognize those schools of pharmacy that have been granted "candidate" status by the ACPE. Staff will provide the exact language at the board meeting.

Update on the Development of Statewide Protocol for Pharmacists to Dispense Emergency Contraception and Recommendation to Pursue Adoption of an Emergency Regulation

On January 30, 2004 the Medical Board of California considered the emergency contraception protocol approved by the Board of Pharmacy at its January 21, 2004 meeting. The discussion

focused on the inclusion of a question regarding the last menstrual period in the protocol. Opposition to this question was articulated by the American College of Obstetricians and Gynecologists (the same opposition was indicated in their testimony before the Board of Pharmacy). The Medical Board delegated consideration of the protocol to a committee of its board, and Board of Pharmacy staff will participate in those discussions. It is expected that the Medical Board committee will meet prior to the Board of Pharmacy meeting in April so that the board may consider any changes that are proposed. The Medical Board anticipates having the protocol on its agenda in May as an action item.

In addition, the staff counsel for the Medical Board indicated that the protocol may have to be adopted as a regulation. Staff will be exploring this with counsel and if necessary, the board may want to take action to adopt the protocol as an emergency regulation.

The Licensing Committee requested that the board's staff counsel confer with the Medical Board's counsel to determine the need to adopt the protocol as a regulation. The committee recommended that the board consider the recommendation from Medical Board at its April meeting and then determine if action is necessary to adopt the protocol as an emergency regulation.

Request for Changes to Business and Professions Code section 4232 and CCR, title 16, section 1732 – 1732.7 Relating to Continuing Education (CE)

The California Pharmacists Association submitted a request to the Board of Pharmacy that it consider amendments to the CE regulations. One reason for this request was that in January 2004, the activities of the Accreditation Evaluation Service (AES) moved from the California Pharmacists Association (CPhA) to the CPhA Educational Foundation. In addition the following changes were included:

- Change the term "continuing pharmaceutical education" to "continuing pharmacy education"
- Change AES from a "continuing education provider and coursework review component of the California Pharmacists Association" to "the accreditation agency for providers of continuing pharmacy education in California"
- Change the role of AES and ACPE from "approvers" to "accreditors"
- Change the ownership AES to the CPhA Educational Foundation
- Change the language from "organization" to "accreditation agency"
- Change the review/audit requirement 10%
- Change the term "certificates of completion" to "statements of credit"
- Require the provider to furnish the "statement of credit" to participants who complete the requirements for course completion
- Require that the material be current in order for it to be considered valid CE

While it appeared that many of the proposed changes to the CE regulations were technical and an effort to update the law, concern was expressed that some changes were substantial. The professional associations agreed to review the proposal and resubmit the request.

Request from Cedars-Sinai Medical Center for a Waiver Pursuant to CCR, title 16, sec. 1706.5 to Conduct a Study with UCSF, School of Pharmacy to Determine the Impact of Technician Checking Technician Filled Unit Dose Cassettes on Patient Care

Dr. Ambrose, Professor of Clinical Pharmacy for UCSF, School of Pharmacy requested a waiver of CCR, title 16, sec. 1793.1(f) and 1793.7(b). The purpose of the waiver is to allow a pharmacy technician in a unit-dose drug distribution system to check another technician. Dr. Ambrose stated that this study is a logical sequel to the successful experimental program that evaluated technicians that concluded in December 2003.

This sequel study will evaluate the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional functions. Such functions require special expertise of pharmacists in the management of drug therapy, from which patients will benefit.

The Cedars-Sinai Medical Center (CSMC) is the sponsoring facility. The proposal requests that the board allow the "tech-check-tech" process to continue at CSMC, while UCSF measures the number and types of medication errors prevented during the equivalent time period that pharmacists would be check medication cassettes. Dr. Ambrose requested that the Board of Pharmacy grant the waiver for two years and that an interim report would be provided at one year. Representatives from CSMC also stated that they would continue to seek legislation to allow the "tech-check-tech" process.

The Licensing Committee recommended that the Board of Pharmacy approve the study.

Statutory Proposal for Application Information

Executive Officer Patricia Harris explained that the applications for the board's 12 regulatory programs require a range of different information from the various applicants. On the advice of counsel, requests for much of the needed information has not been included on applications because of a concern regarding the specific legal authority to request the information. Accordingly, staff developed a legislative proposal for inclusion in the 2004 Omnibus Bill. This proposal is intended to provide the board with clear statutory authority to request information needed to evaluate the qualifications of any applicant. This will allow the board to include necessary information on application forms without adopting regulations to do so.

The proposal is to clarify the basic information that is requested on application forms, which is consistent with the relevant law requirements to obtain a license or permit from the board. Concern was expressed that the proposal may be too broad. Modifications to the proposal would be provided.

The Licensing Committee recommended that the Board of Pharmacy support the legislative proposal, noting that proposed modifications will be provided to address the concern that the language is overly broad.

Overview of Scholarship Process for Pharmacist

At the January meeting, the board agreed to pursue a statutory change to clarify the $25 contribution that can be made to the pharmacist loan repayment program. During this discussion, clarification was sought about the loan program and how it works. Staff agreed to provide more information at the next meeting. In response, Legislation Chief Paul Riches explained that Assembly Bill 2935 (Chapter 1138, Statutes of 2002) established the California Pharmacist Scholarship and Loan Repayment Program in the Office of Statewide Health Planning and Development (OSHPD). The bill established a mechanism for pharmacists and pharmacies to contribute $25 to a fund that would provide scholarships or loan forgiveness to pharmacists and pharmacy students who committed to serve in medically underserved communities.

The statute specifies that the program will only be implemented to the extent funding is made available. It permits both the contributions by renewing pharmacists and pharmacies and any other source of funding that can be identified and appropriated by the Legislature.

The bill also specifies that the program shall be administered using the criteria employed by the National Health Service Corps scholarship and loan repayment programs and excerpts from those program bulletins were provided. As a general matter, the programs provide funding to students and graduates who commit to provide health services in medically underserved communities for a two-year period. Funding is capped at $25,000 per year based on either the actual educational expenses or the total amount of qualified educational loans outstanding for the candidate.

Candidates are selected generally based on financial need and having characteristics that indicate a tendency to remain in the underserved community after their commitment has been completed.

Strategic Plan Review and Update

The Licensing Committee reviewed the strategic plan and did not make any changes.

ACPE Evaluation of the Doctor of Pharmacy Program of Thomas J. Long School of Pharmacy

Ms. Harris reported that the Accreditation Council for Pharmacy Education (ACPE) is responsible for the evaluation of pharmacy education. When ACPE performs an evaluation of a California school, a representative from the Board of Pharmacy is invited to participate on the evaluation team.

ACPE invited the board to participate on the team that evaluated the Doctor of Pharmacy program of Thomas J. Long School of Pharmacy and Health Sciences at the University of Pacific on February 17-19, 2004. Board Member Stan Goldenberg participated and will report on the evaluation process and his experience at the April board meeting.

Adjournment

Licensing Committee Chair Clarence Hiura adjourned the meeting at 11:45 a.m.

ATTACHMENT L

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NO ACTION
REPORT ONLY

COMPETENCY COMMITEE REPORT TO THE BOARD MEMBERS FROM THE LICENSING COMMITTEE CLARENCE HIURA, CHAIR APRIL 9, 2004

1. **Report on the Contracts for the California Pharmacist Jurisprudence Exam (CPJE) and the North American Pharmacist Licensure Examination (NAPLEX)**

   On March 11, 2004, the contract with Experior Assessment, Inc. was signed to administer the CPJE for the board. On April 2, 2004, the contract with the National Association of Boards of Pharmacy (NABP) was signed to administer the NAPLEX for the board. With the signing of both contracts, the board is continuing to develop procedures to allow for a smooth transition for the exam applicants.

2. **CPJE Handbook and Sample Questions**

   In February 2004, the board posted on the Web site the CPJE Handbook and Sample Questions to assist exam candidates in their preparation for the CPJE.

3. **Competency Committee Meetings**

   The Competency Committee met for two days in February and March 2004 to develop exam questions. Their next meeting is scheduled for May 26 and 27, 2004.

ATTACHMENT M

Board of Pharmacy Licensing Statistics - Fiscal Year 2003/04

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	16	22	71	72	54	2	157	145	n/a				539
Intern pharmacist	89	195	405	240	184	75	88	154	n/a				1430
Pharmacy technician	555	500	793	562	658	942	654	335	n/a				4999
Foreign educated pharmacists (evaluations)	4	9	98	33	15	18	18	67	n/a				262
Pharmacy	38	35	51	24	37	23	36	26	42				312
Sterile Compounding	20	10	6	6	10	7	9	2	6				76
Clinics	12	22	14	16	19	13	11	5	19				131
Hospitals	1	2	3	0	3	1	5	1	1				17
Nonresident Pharmacy	9	4	6	4	6	2	4	4	3				42
Licensed Correctional Facility	0	1	0	0	0	0	0	1	0				2
Hypodermic Needle and Syringes	4	9	5	4	4	4	7	7	5				49
Out of State Distributor	5	9	6	2	6	6	6	7	9				56
Wholesalers	8	6	7	5	8	12	16	11	6				79
Veterinary Food-Animal Drug Retailer	1	0	0	0	0	0	0	0	0				1
Exemptees	51	47	61	39	33	25	37	33	47				373
Issued													
Pharmacist	11	421	167	88	29	8	5	8	4				741
Intern pharmacist	79	201	285	301	153	63	81	68	79				1310
Pharmacy technician	660	1105	456	903	483	621	1173	548	649				6598
Pharmacy	37	51	47	39	32	22	20	32	34				314
Sterile Compounding	95	11	6	6	0	1	13	11	10				153
Clinics	17	12	16	33	14	5	17	7	13				134
Hospitals	1	7	3	2	1	1	1	0	0				16
Nonresident Pharmacy	2	9	10	8	2	8	10	3	1				53
Licensed Correctional Facility	0	1	0	0	1	0	0	0	0				2
Hypodermic Needle and Syringes	2	3	6	6	1	2	3	2	6				31
Out of State Distributor	6	11	5	7	8	4	2	7	1				51
Wholesalers	28	6	9	8	2	10	9	7	7				86
Veterinary Food-Animal Drug Retailer	0	0	0	5	1	0	0	0	0				6
Exemptees	58	45	49	41	18	14	57	38	18				338

Board of Pharmacy Licensing Statistics - Fiscal Year 2003/04

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacist Examination	u/a	u/a	u/a	u/a	u/a	u/a	u/a	u/a	131				131
Intern pharmacist	u/a	u/a	11	u/a	u/a	32	u/a	u/a	44				44
Pharmacy technician													
Foreign educated pharmacists (evaluations)	u/a	u/a	18	u/a	u/a	33	u/a	u/a	11				11
Pharmacy	69	72	74	59	43	44	60	54	54				54
Sterile Compounding	54	53	53	53	50	56	52	42	37				37
Clinics	61	79	77	60	44	52	46	44	42				42
Hospitals	40	10	10	8	7	7	11	12	11				11
Nonresident Pharmacy	54	40	34	30	33	27	21	22	19				19
Licensed Correctional Facility	0	0	0	8	0	0	0	1	0				0
Hypodermic Needle and Syringes	5	14	8	5	8	10	14	15	13				13
Out of State Distributor	46	51	41	29	23	24	28	25	35				35
Wholesalers	42	48	27	24	27	28	35	29	39				39
Veterinary Food-Animal Drug Retailer	1	1	1	1	0	0	0	1	1				1
Exemptees	114	103	104	88	156	167	147	142	171				171
Change of Pharmacist-in-Charge													
Received	170	170	224	164	192	137	152	171	189				189
Processed	114	207	218	158	183	108	165	196	132				132
Pending	139	102	108	114	123	152	139	114	171				171
Change of Exemptee-in-Charge													
Received			3	6	4	3	0	5	3				3
Processed			3	3	3	0	0	4	3				3
Pending			0	3	4	7	7	8	8				8
Change of Permits													
Received	49	57	60	27	30	35	28	38	24				24
Processed	55	10	121	34	18	19	13	5	70				70
Pending	135	182	121	114	126	142	157	190	144				144
Discontinuance of Business													
Received	9	8	16	6	21	14	14	9	22				22
Processed	0	33	11	33	15	0	18	0	35				35
Pending	47	22	27	0	6	20	16	25	12				12

Board of Pharmacy Licensing Statistics - Fiscal Year 2003/04

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacist	2567	1115	1236	1408	898	1469	1292	994					10979
Pharmacy technician	1964	971	1216	1352	939	1425	1345	1161					10373
Pharmacy	970	180	836	506	194	379	426	500					3991
Sterile Compounding	0	0	0	0	0	0	0	5					5
Clinics	89	49	36	38	42	61	64	51					430
Nonresident Pharmacy	25	12	9	13	9	12	21	13					114
Hypodermic Needle and Syringes	33	15	20	28	18	26	25	16					181
Out of State Distributor	44	12	22	21	15	26	23	20					183
Wholesalers	76	24	29	30	20	41	43	33					296
Veterinary Food-Animal Drug Retailer	4	6	2	0	1	0	1	1					15
Exemptees	252	74	103	124	76	155	158	132					1074

Licensing Committee

2003-2004
Third Quarter Report
July 1, 2003 – March 31, 2004

Goal 2: **Ensure the professional qualifications of licensees.**

Outcome: **Qualified licensees.**

Objective 2.1: **Issue licenses within three working days of a completed application by June 30, 2005.**

Measures: **Percentage of licenses issued within 3 working days.**

A new tracking system is in the testing phase and should be fully implemented by November 1, 2003. Therefore, some of the information are estimates and will be notated with an asterisk.

Tasks:

1. **Review 100 percent of all applications within 7 working days of receipt.**

   Note: Pharmacists examination applications are not being processed because of the changes outlined in SB 361. Upon completion of the procedures and revision of the necessary forms, the board will resume this workload.

	Apps. Received:			**Average Days to Process:**		
	Q1	Q2	Q3	Q1	Q2	Q3
Pharmacy Intern	689	499*	242**	3	7-10	10-14
Pharmacy Technicians	1848	2162*	989**	15	13	5-7
Foreign Graduates	111	66*	85**	n/a	n/a	n/a
Pharmacies	131	88	104	7	13	6
Non-Resident Pharmacy	19	12	11	23	25	27
Wholesaler	21	25	20	7	8	18
Veterinary Drug Retailer	1	0	0	n/a	33	0
Exemptee	159	97	118	6	4	30
Out-of-State Distributor	20	14	21	15	18	13
Clinics	48	48	35	8	9	6
Hypo Needle & Syringe	18	12	8	5	17	7
Sterile Compounding	36	23	17	7	7	3

* denotes updated to include December 2003 information available at time of report development.
**denotes January and February 2004 information available at time of report development.

2. **Process 100 percent of all deficiency documents within 3 working days of receipt.**

Average days to process deficiency:

	Q1	Q2	Q3
Pharmacist	3	3	3
Pharmacy Intern	3	7-10	7-10
Pharmacy Technician	14	17	5-10
Foreign Graduate	n/a	n/a	n/a
Pharmacies	19	15	16
Non-Resident Pharmacy	25	44	67
Wholesaler	12	8	21
Veterinary Drug Retailer	n/a	7	0
Exemptee	38	38	17
Out-of-State Distributor	12	11	11
Clinics	19	12	20
Hypo Needle & Syringe	7	2	2

3. **Make a licensing decision within 3 working days after all deficiencies are corrected.**

Average days to issue license:

	Q1	Q2	Q3
Pharmacist	1	1	1
Pharmacy Intern	1	1	1
Pharmacy Technician	10	10	5-7
Foreign Graduate	n/a	n/a	n/a
Pharmacies	14	16	9
Non-Resident Pharmacy	64	13	34
Wholesaler	4	3	6
Veterinary Drug Retailer	n/a	1	0
Exemptee	1	27	3
Out-of-State Distributor	9	2	4
Clinics	12	6	1
Hypo Needle & Syringe	6	2	3

4. **Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.**

	Q1	Q2	Q3
Pharmacist	599	125	17
Pharmacy Intern	565	517	228
Pharmacy Technician	2221	2007	2370
Foreign Graduate	n/a	n/a	n/a
Pharmacies	147	99	95
Non-Resident Pharmacy	21	18	15
Wholesaler	43	20	23
Veterinary Drug Retailer	0	1	0
Exemptee	152	82	155
Out-of-State Distributor	22	17	10
Clinics	45	52	34
Hypo Needle & Syringe	11	9	11

5. **Withdrawn licenses to applicants not meeting board requirements.**

	Q1	Q2	Q3
Pharmacy Technician	10	5	6
Pharmacies	4	5	1
Non-Resident Pharmacy	2	3	4
Clinics	0	10	13

Objective 2.2: **Implement at least 50 changes to improve licensing decisions by June 30, 2005.**

Measure: **Number of implemented changes.**

Tasks:

1. **Review Pharmacist Intern Program.**

9/03 *Discussed at Licensing Committee Meeting. No recommendations were made. Will revise intern reporting affidavits.*

12/03 *Discussed proposed statutory changes and Licensing Committee recommended board approval.*

1/04 *Board approved proposed statutory changes. Will be added to 2004 omnibus bill. Board recognized the School of Pharmacy at Lake Erie College of Osteopathic Medicine for purposes of issuing an intern registration to a student from this school. Staff to develop process to approve new schools of pharmacy not ACPE accredited.*

3/04 *Discussed proposed regulation change to issue an intern registration to an applicant enrolled in school of pharmacy that has a "candidate" status with ACPE. Licensing Committee recommended board approval.*

2. Implement changes to the Pharmacy Technician Program.

a. Use PTCB as a qualifying method for registration.

b. Eliminate clerk-typist from pharmacist supervisory ratio.

c. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology.

9/03 *Governor signed SB 361. New changes will be implemented 11/04. Regulation changes are proposed to the board. Application forms have been revised.*

10/03 *Board approved proposed regulation changes. Regulation proposal pending with Legislative/Regulation Committee.*

12/03 *New application forms made available on website.*

1/04 *New program requirements are implemented.*

3. Administer a pharmacist licensure exam more than twice a year.

9/03 *Governor signed SB 361 to implement NAPLEX and California specific exam to be administered quarterly via computer. The Licensing Committee recommended regulation changes to implement new examination program.*

10/03 *Board approved proposed regulation changes.*

12/03 *Proposed regulation changes are pending with the Legislative/Regulation Committee.*

12/03 *Revised application and instruction forms.*

12/03 *Finalized contracts for the new examinations.*

1/04 *Started processing applications for pharmacist licensure examination.*

3/04 *Contract for California specific examination was approved.*

4/04 *NAPLEX contract was approved.*

4. **Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.**

9/03 *Developed content outline for California specific exam and made available on board's website. Additional test questions identified by Competency Committee for inclusion in Candidate's Review Guide.*

12/03 *Worked on new Candidate Review Guide for the California specific examination.*

3/04 *Candidate Review Guide for California specific examination and update on examination process added to the board's Web site.*

4/04 *Presentation to the graduating class on the exam process are scheduled for April and May.*

5. **Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.**

6. **Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.**

8/03 *Competency Committee met for two days and finalized content outline. Reviewed question bank.*

9/03 *Competency Committee met for two days and developed questions.*

10/03 *Competency Committee met for two days and developed questions.*

11/03 *Competency Committee met for three days and developed questions.*

2/04 *Competency Committee met for two days and developed questions.*

3/04 *Competency Committee met for two days and developed questions.*

3/04 *Licensing Committee recommended that Competency Committee be restructured to a two-tier structure that would be a group of item writers to develop questions for the CPJE and a core committee that would develop and oversee the CPJE administration.*

7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.

9/03 *Reported that 126 sterile compounding licenses have been issued since July 1.*

12/03 *Reported that 151 sterile compounding licenses have been issued since July 1.*

4/04 *Reported that xxx sterile compounding licenses have been issued since July 1.*

8. Issue temporary permits whenever change of ownership occurs.

9/03 *1st Quarter - 24 temporary permits issued.*

1/04 *2nd Quarter – 12 temporary permits issued.*

4/04 *3rd Quarter – 32 temporary permits issued*

9. Establish means for licensee to renew permits on line.

8/03 *NABP is establishing a program that will allow states to establish criteria for licenses to be renewed on line through NABP. The board has requested Legal Affairs to review this as a possible option for the board.*

10. Implement Changes to Facilities Licensure Requirements

9/03 *Proposed statutory changes to the licensure requirements for wholesale facilities. Recommended board support requirements.*

9/03 *Proposed statutory changes that would clarify the licensure requirements for facilities. Would prohibit facilities from being located in a personal residence and clarifies that the board issues a permit at one premise which is a separate operation. Recommended board support.*

10/03 *Board approved proposed statutory changes for wholesale facilities and other licensure requirements.*

12/03 *Statutory proposals are pending with the Legislative/Regulation Committee.*

11. Review the Ownership of Pharmacies

10/03 *Board determined that a Limited Liability Company can own a pharmacy.*

12. Review the law regarding candidates who fail the pharmacist licensure exam 4 times or more who are required to take an additional 16 units of pharmacy education.

3/04	*Recommend that this provision be extended to the board's next sunset review in 2006 due to the change in examination format. Obtained clarification from counsel that with new examination format, an applicant has 4 opportunities to pass NAPLEX and 4 opportunities to pass CPJE.*
3/04	*Board is required to report to the Legislature by December 31, 2004, the effect of this law in 4 areas. Draft report will be provided at April Board meeting.*
	13. Evaluate application requirements for all licenses.
3/04	*Proposed a change for inclusion in the 2004 omnibus bill to give clear statutory authority to request information needed to evaluate the qualifications of any applicant.*

Objective 2.3:	**Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005.**
Measure:	**Number of public policy initiatives evaluated.**

Tasks:

1. Explore the need to regulate pharmacy benefit managers.

9/03 *Ad Hoc Committee held 3rd meeting. Requested completion of Sunrise Questionnaire. Recommended that the board not take action.*

10/03 *Board agreed with recommendation, but will continue to "watch" the issue.*

2. Explore the need to regulate drugs labeled for "veterinary use only."

9/03 *SB 175 was introduced and signed (Chapter 250, Statutes 2003).*

3. Explore the importation of drugs from foreign countries.

7/03 *Discussed at July Enforcement Committee and board meetings.*

9/03 *Discussed at September Enforcement Committee.*

10/03 *Discussed at October Board meeting.*

12/03 *Discussed at December Enforcement Committee meeting.*

1/04 *Discussed at January Board meeting.*

3/04 *Discussed at March Enforcement Committee meeting.*

4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.

9/03 *Legislation and Regulation Committee held informational hearing – Completed.*

5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding

12/03 *Licensing Committee requested participation of Board Members John Tilley and Ken Schell and Supervising Inspector Dennis Ming.*

3/04 *Held first meeting of Workgroup on Compounding and developed list of issues to address.*

6. Approve a statewide protocol for emergency contraception (ec) to permit pharmacists to furnish ec pursuant SB 490 (Chapter 651, Statutes of 2003.)

	12/03	*Recommended approval of protocol submitted by the Pharmacy Access Partnership and ACOCT.*
	1/04	*Board approved protocol*
	1/04	*Medical Board of California (MBC) did not act on protocol and delegated to committee to review and address concerns.*
	3/04	*Reported status that MBC had not yet provided a revision. Advised that protocol must be adopted as regulation.*
	7. Consider a waiver pursuant to CCR, Title 16, Section 1706.5 from Cedars-Sinai Medical Center (CSMC) to conduct a study with UCSF, School of Pharmacy to determine the impact of using technician check technicians to fill unit dose cassettes on patient care.	
	1/04	*UCSF presented the final report on the study on the evaluation of pharmacy technicians in a unit-dose distribution system. The study began May 1998 and ended December 31, 2003.*
	3/04	*CSMC is requesting a waiver in order to conduct a sequel study with UCSF to evaluate the impact of pharmacist in the prevention of medication errors with prescribing and administering of medications instead of checking unit-dose cassettes.*
Objective 2.4:	**Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.**	
Measure:	**Percentage of cashiered application and renewal fees within 2 working days.**	
Tasks:	**1. Cashier application fees.**	
	9/03	*1st Quarter - The average processing time for processing new application fees is 2-3 working days.*
	1/04	*2nd Quarter - The average processing time for processing new application fees is 2-3 working days.*
	4/04	*3rd Quarter – The average processing time for processing new application fees is 2-3 working days.*
	2. Cashier renewal fees.	
	9/03	*The board lost its renewal cashier in October 2001 and has been unsuccessful in obtaining a freeze waiver to fill this position. The average processing time for processing renewal fees in house is 10 days.*
	9/03	*1st Quarter - Average processing time for central cashiering is 2-3 weeks.*

	1/04	*2nd Quarter - Average processing time for central cashiering is 2-3 weeks.*
	4/04	*3rd Quarter – Average processing time for central cashiering is 2-3 weeks.*
Objective 2.5:		**Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2005.**
Measure:		**Percentage response for verifying licensing information within 5 working days.**
Tasks:		**1. Respond to requests for licensing verification.**
	9/03	*1st Quarter – Processed 261 license verifications.*
	1/04	*2nd Quarter – Processed 178 license verifications.*
	4/04	*3rd Quarter – Processed 245 licensure verifications.*
Objective 2.6:		**Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.**
Measure:		**Percentage of licensing records changes within 5 working days**
Tasks:		**1. Make address and name changes.**
	9/03	*1st Quarter – Processed 1,994 address changes.*
	1/04	*2nd Quarter – Processed 2,679 address changes.*
	4/04	*3rd Quarter – Processed 1,743 address changes.*
		2. Process discontinuance of businesses forms and related components.
	9/03	*1st Quarter – Processed 34 discontinuance- of-business forms. Processing time is 40 days.*
	1/04	*2nd Quarter - Processed 26 discontinuance- of-business forms. Processing time is 7 days.*
	4/04	*3rd Quarter - Processed 52 discontinuance- of-business forms. Processing time is 24 days.*
		3. Process changes in pharmacist-in-charge and exemptee-in-charge.
	9/03	*1st Quarter – Processed 539 pharmacist-in-charge changes. Average processing time is 130 days. Processed 3 exemptee-in-charge changes. The average processing time is 14 days.*

1/04	*2nd Quarter – Processed 225 pharmacist-in-charge changes. Average processing time is 14 days. Processed 6 exemptee-in-charge changes. The average processing time is 8 days.*
4/04	*3rd Quarter – Processed 380 pharmacist-in-charge changes. Average processing time is 37 days. Processed 7 exemptee-in-charge changes. The average processing time is 7 days.*
	4. Process off-site storage applications.
9/03	*Processed 43 off-site storage applications.*
12/03	*Processed 17 off-site storage applications.*
4/04	*Processed 36 off-site storage applications.*
	5. Process change-of-permit applications.
9/03	*1st Quarter – Processed 185 applications. Average processing time is 130 days.*
1/04	*2nd Quarter – Processed 71 applications. Average processing time is 12 days.*
4/04	*3rd Quarter – Processed 120 applications. Average processing time is 40 days.*